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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A61M 37/00, 5/14

A2

(11) International Publication Number: WO 89/ 06553

(43) International Publication Date: 27 July 1989 (27.07.89)

(21) International Application Number: PCT/US89/00273

(22) International Filing Date: 23 January 1989 (23.01.89)

(31) Priority Application Numbers: 147,414
217,004

(32) Priority Dates: 25 January 1988 (25.01.88)
8 July 1988 (08.07.88)

(33) Priority Country: US

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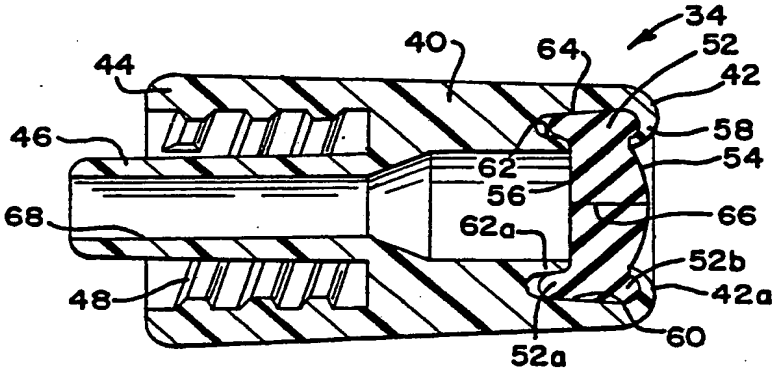
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: PRE-SLIT INJECTION SITE AND TAPERED CANNULA



(57) Abstract

A pre-slit injection site (34) includes a housing (40) with a flow path therethrough. A first end (42) of the housing (40) carries a pre-slit septum (52). One form of a blunt cannula (98), usable with the injection site (34), carries a locking member (100). When the pre-slit injection site (34) slidably receives the blunt cannula (98), the locking member (100) latches to the injection site (34) and creates a mechanically coupled unit. Another form of the cannula (280) includes a tube having a tapered distal end regi n (298) and having el ngate discharge sl ts (294) for reducing contact surface area and for directing the flow laterally out f the cannula. The cannula may also include a rounded lead post (330), an annular barb (394), and axially oriented gr ves (268).

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PRE-SLIT INJECTION SITE AND TAPERED CANNULA

Field of the Invention

The invention pertains to coupling systems usable to transfer materials from one flow conduit to another. More particularly, the invention pertains to two-part coupling members with a first part including a pre-slit septum and second part including a blunt cannula. The pre-slit septum slidably receives the blunt cannula to effect the coupling.

Background of the Invention

Injection sites usable with pointed cannulae have long been known. For example, such sites can be formed with a housing having a fluid flow path therein. A septum is positioned in the housing closing the fluid flow path.

One injection site usable with a piercing cannula is disclosed in U.S. Patent No. 4,412,573 to Zbed entitled "Injection Site." The Zbed patent is assigned to the assignee of the present invention.

The pointed cannula can be forced through the septum into fluid flow communication with the flow path in the housing. Known injection sites usable with a piercing cannula can be physically damaged by repetitive piercing caused by the sharp cannula. This damage, known as coring or laceration, can result in subsequent leakage.

Due to problems associated with infectious agents, personnel using such pointed cannulae do so with great care. Notwithstanding careful and prudent practice, from time to time, accidents do occur and individuals using such pointed cannulae jab themselves.

Injection sites usable with a blunt cannula are also known. For example, U.S. Patent No. 4,197,848 issued to Garrett, et al., entitled "Closed Urinary Irrigation Site" and assigned to the assignee of the present invention discloses one such injection site. That injection site is a relatively low pressure device having a relatively thin, molded, sealing member. The sealing member has an opening therethrough.

A blunt cannulae can be forced through the sealing member placing the cannulae into fluid flow communication with a fluid flow pathway in the injection site.

Injection sites of the type noted above usable with a blunt cannula have the advantage that the blunt cannula will not pierce the skin of a user. On the other hand, it is important that the pre-slit injection

sit reseal with nough force that fluids do not ooze therefrom and that airborne particulate matter, bacterial or viral matter do not enter therethrough.

Hence, there continues to be a need for a pre-slit injection site which can be used with a variety of solutions and over a range of fluid pressures. Further, there continues to be a need for such a pre-slit injection site which will reliably reseal even after many insertions of the blunt cannula.

Such an injection site should be able to receive a large number of insertions of the cannula without displaying reseal failure. Such an injection site should provide for improved alignment of the cannula on insertion. Improved alignment will result in less chance of damage to the injection site after repeated insertions of the cannula. Preferably, the injection site would also be usable with a pointed cannula. Preferably, a pre-slit injection site usable with a blunt cannula will provide a reasonable level of insertion force such that health care personnel will readily be able to insert the blunt cannula, yet the cannula will not easily fall from or drop out of contact with the septum.

Summary of the Invention

In accordance with the invention, an easily wipeable injection site usable with a blunt cannula is provided. The injection site includes a housing which defines a fluid flow channel therethrough. The housing has a first and a second end.

A flexible sealing member is carried by the housing for sealing the first end. The sealing member has a resealable opening therein. The sealing member also is formed with a curved exterior peripheral surface such that the blunt cannula can be sealingly inserted through the opening and placed in fluid flow communication with the flow path. Further, the blunt cannula can be removed from the opening with a sealing member then interacting with the housing so as to reseal the opening.

The housing can also be formed with the first end including an annular channel underlying the sealing member. The sealing member is subjected to radially directed forces by a tapered surface of the first end of the housing. These forces tend to reseal the opening in the sealing member.

The sealing member can be a cylindrically shaped rubber member. The first end of the housing can include an interior tapered surface for receiving the sealing member and for applying the radially directed forces to the sealing member.

A retaining member carried by the first end of the housing can be used to retain the sealing member within the housing. The retaining member can be generally U-shaped. Alternately, the retaining member can be formed as a coiled spring.

The retaining member applies axially directed forces to the sealing member. In one embodiment of the invention, the retaining member deflects the sealing member and forms a curved exterior peripheral surface thereon. The curved exterior peripheral surface is an easily wipeable surface.

The retaining member deflects or distorts the upper and lower peripheral edges slightly as a result of applying axial forces thereto. When the blunt cannula is inserted into the slit in the sealing member, an annular interior peripheral region of the sealing member deforms further and fills, at least in part, the annular channel.

Deformation of this annular peripheral region results in an insertion force in a range of 2.0 pounds (.7564 kilograms) to 5.0 pounds (1.891 kilograms). Preferably, the insertion force will have a value of the order of 2.0 pounds (.7564 kilograms).

The resealable opening in the sealing member can extend entirely through that member. Alternately, the resealable opening can extend only partway therethrough. In this embodiment, the end of the blunt cannula will be used to tear through the remainder of the sealing member.

The sealing member can be formed in two parts. An exterior cylindrical portion can be slit completely. An interior cylindrical unslit portion can be provided to seal the site until the blunt cannula is inserted therethrough the first time.

The interior surface of the first end can be formed with the taper in a range on the order of 5 degrees to 20 degrees. Preferably, the interior surface will have a taper on the order of 12 degrees. This tapered surface permits the use of a cylindrically shaped sealing member.

To provide for leak-free insertion, the length of the slit in the sealing member must be less than one-half the circumference of the cannula being inserted therethrough. Hence, the slit length may exceed the diameter of the cannula being inserted. In addition, the slit length must be great enough, given the elastic limit of the sealing member, to prevent tearing during insertion.

Further, in accordance with the invention, a

coupling system for coupling first and second fluid flow members together is provided. The coupling system includes an injection site which is affixed to the first fluid flow member. The injection site includes a housing. The housing has a fluid flow path therethrough.

A sealing member is carried by the housing. The sealing member has a resealable opening therein.

An annular retaining member is carried by the housing and cooperates with the housing to retain the sealing member therein. Radially directed forces are applied to the sealing member by the housing, thereby urging the opening into a resealed condition.

A blunt cannula, affixed to second fluid flow member, has a fluid flow path therethrough. The cannula carries a locking member for lockingly engaging the housing when the cannula extends through the opening of the sealing member. When so positioned, the two fluid flow members are placed into fluid flow communication.

The locking member can include a Luer-type twist lock fitting. Alternately, the locking member can include slidably engageable members which are responsive to axial movement of the injection site and the cannula toward one another.

In accordance with further aspects of this invention, the blunt cannula may be provided with features that facilitate insertion into the injection site, enhance fluid flow or dispersion, increase tug resistance, and reduce kickback.

In particular, one embodiment of the cannula includes a tube with a plurality of elongate discharge slots adjacent the distal end. The fluid changes direction as it passes laterally through the slots and out of the tube. The flow area of the slots exceeds the flow area inside the tube. This slot structure enhances fluid flow and inspersion characteristics. In addition, the slots decrease the contact surface area on the tube exterior so as to facilitate insertion.

In a further modification, th cannula includes a lead post on the tube distal end to guide the cannula through the slit in the injection site.

In another cannula embodiment, the tube is generally cylindrical and the fluid discharges directly from an open end of the tube. The exterior surface of the tube is provided with grooves to reduce the contact surface area.

In still another cannula embodiment, the tube has a cylindrical portion and a tapered distal end portion which are each about equal in length. The taper facilitates insertion, and the remaining cylindrical portion reduced kickback.

In yet another embodiment, the cannula includes an annular barb which functions to reduce kickback.

Other advantages of a blunt plastic cannula in accordance with the invention, relative to conventional steel needles include a higher fluid flow rate capacity and a simpler one-piece plastic design.

Numerous other advantages and features of the present invention will become readily apparent from the following detailed description of the invention and the embodiments thereof, from the claims and from the accompanying drawings in which the details for the invention are fully and completely disclosed as a part of this specification.

Brief Description of the Drawings

Figure 1 is a side elevational view, partly in section, of a prior art pre-slit injection site and an associated blunt cannula;

Figure 2A is a view in perspective of a catheter positioned in the hand of a patient with a pre-slit injection site in accordance with the present invention positioned adjacent thereto;

Figure 2B is a perspective view of the catheter of Figure 2A with a pre-slit injection site in accordance with the present invention rotatably affixed thereto;

Figure 3 is an enlarged side elevational view in a section of a pre-slit injection site in accordance with the present invention formed on a body having a luer twist-lock type connector for coupling to a catheter;

Figure 4A is an exploded view of a pre-slit injection site, a shielded blunt cannula and a syringe prior to being coupled together;

Figure 4B is an enlarged, side elevational view in section of the pre-slit injection site, the shielded blunt cannula and the syringe of Figure 4A coupled together to form a sealed fluid flow system;

Figure 5A is a view in perspective of a pre-slit injection site prior to engaging a blunt cannula carrying a locking member;

Figure 5B is an enlarged side elevational view, partly broken away, illustrating the interrelationship between the pre-slit injection site and the blunt cannula of Figure 5A;

Figure 6 is an overall view of a container, an associated solution administration set and a pre-slit injection site in accordance with the present invention;

Figure 7 is an enlarged side elevational view, partly broken away illustrating the relationship between selected elements of Figure 6;

Figure 8 is a side elevational view, partly

broken away illustrating an alternate shielded cannula in accordanc with the present invention;

Figure 9 is a side elevational view, partly in section, of a pre-slit injection site mounted on a fragment of a solution container;

Figure 10 is a side elevational view of a fragment of a solution container carrying, as a single port, a pre-slit injection site;

Figure 11 is a side elevational view of the injection site and the fragmentary container of Figure 10 prior to being engaged with a shielded cannula carried by a syringe;

Figure 12 is an enlarged side elevational view, partly in section, of a coupling system with a pre-slit injection site partly coupled to a blunt cannula;

Figure 13 is an enlarged side elevational view, partly in section, of the coupling system of Figure 12 subsequent to engagement of the two coupling members;

Figure 14 is a side elevational view, partly broken away, of a spike connector carrying a pre-slit injection site in accordance with the present invention;

Figure 15 is an enlarged side elevational view of a Y-connector in section carrying a pre-slit injection site in accordance with the present invention;

Figure 16 is an enlarged fragmentary side elevational view in section of a coupling member carrying a pre-slit injection site where the slit extends only partway through the septum;

Figure 17 is a perspective view of a burette solution administration set carrying a pre-slit injection site in accordance with the present invention;

Figure 18 is a view of part of a burette solution administration set carrying a pre-slit injection site being coupled to a shielded blunt cannula;

Figure 19 is a step in the method of making a

pre-slit injection site in accordance with the present invention;

Figure 20 is another step in the method of making a pre-slit injection site in accordance with the present invention;

Figure 21 is an initial phase of a final step in making a pre-slit injection site in accordance with the present invention;

Figure 22 is an intermediate phase of the final step in a method of making a pre-slit injection site in accordance with the present invention;

Figure 23 is a final phase of the final step in a method of making a pre-slit injection site in accordance with the present invention;

Figure 24 illustrates an initial phase in an alternate step of making a pre-slit injection site in accordance with the present invention;

Figure 25 illustrates a final phase of the alternate step in a method of making an injection site in accordance with the present invention;

Figure 26 illustrates yet another alternate step in a method of making a pre-slit injection site in accordance with the present invention;

Figure 27 is an enlarged, fragmentary cross-sectional view of another embodiment of an injection site in accordance with the present invention;

Figure 28 is a cross-section view taken generally along the plane 28-28 in Figure 27;

Figure 29 is an end view of another embodiment of the cannula in accordance with the present invention;

Figure 30 is a cross-section view taken generally along the plane 30-30 in Figure 29;

Figure 31 is an end view of another embodiment of the cannula in accordance with the present invention;

Figure 32 is a cross-sectional view taken generally along the plane 32-32 in Figure 31;

Figure 33 is a cross-sectional view taken generally along the plane 33-33 in Figure 32;

Figure 34 is an end view of another embodiment of the cannula in accordance with th present invention;

Figure 35 is a fragmentary, side elevational view of the embodiment of the cannula illustrated in Figure 34;

Figure 36 is a cross-sectional view taken generally along the plane 36-36 in Figure 34;

Figure 37 is a cross-sectional view taken generally along the plane 37-37 in Figure 36;

Figure 38 is an end view of another embodiment of the cannula according to the present invention;

Figure 39 is a cross-sectional view taken generally along the plane 39-39 in Figure 38;

Figure 40 is a cross-sectional view taken generally along the plane 40-40 in Figure 39;

Figure 41 is an end view of another embodiment of the cannula according to the present invention;

Figure 42 is a cross-sectional view taken generally along the plane 42-42 in Figure 41;

Figure 43 is an end view of another embodiment of the cannula according to the present invention;

Figure 44 is a cross-sectional view taken generally along the plane 44-44 in Figure 43; and

Figure 45 is a view in section of another insertion member for a blunt cannula.

Detailed Description of the Preferred Embodiments

While this invention is susceptible of embodiment in many different forms, there are shown in the drawing and will be described herein in detail specific embodiments thereof with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the specific embodiments illustrated.

A prior art pre-slit injection site 10 and associated blunt cannula 12 are illustrated in Figure 1. The prior art injection site 10 has a cylindrical housing 14 with a fluid flow path 16 therethrough. A first end 18 of the housing 14 is closed with a relatively thin disc-shaped resealable member 20. The member 20 has a resealable opening 22 therein.

The member 20 is a molded septum with an integrally formed skirt 20a. The skirt 20a is oriented generally perpendicular to the portion of the septum with the opening 22.

The cannula 12 includes a body portion 24 which carries at a first end a hollow, cylindrical, blunt piercing member 26. As the cannula 12 is moved in a direction 28 toward the first end 18 of the injection site 10, the member 26 slidably engages the opening 22. The sealing member 20 is then deformed adjacent the opening 22 and the number 26 extends into the flow path 16. A fluid flow path through the cannula 12 will then be in fluid flow communication with the flow path 16 via the hollow piercing member 26.

In contradistinction to the prior art pre-slit injection site 10 of Figure 1, Figures 2A and 2B illustrate a pre-slit injection site 34 being coupled to a peripheral venous catheter 36. The catheter 36 is shown in fluid flow communication with a vein in a hand H of a patient. The catheter 36 carries at a proximal end 38 a luer-type female twist lock connector 41.

The pre-slit injection site 34 is formed with

a cylindrical housing 40 having a first end 42 and a second end 44.

Carried by the housing 40, adjacent the second end 44 is a hollow cylindrical fluid flow member 46. The member 46 slidably engages a receiving member in the housing 38 of the catheter 36, thereby providing a sterile fluid flow coupling as is well known and conventional.

A plurality of internal male luer-type threads 48 is carried by the housing 40 adjacent the second end 44. The threads 48 will engage the flange member 41 when the injection site 34 is rotated in a direction 50. When so coupled together, the catheter 36 and the injection site 40 provide a sealed coupling through which fluids may be injected into the vein of the hand H.

Figure 3 illustrates, in section, further details of the injection site 34. A resealable septum 52 is carried by the first end 42 of the housing 40. The septum 52 includes first and second spaced apart surfaces 54 and 56 respectively. The surface 54 has been forced into a dome-like shape by annular, U-shaped, swaged end members 58 carried by the first end 42. The dome-like shape of the surface 54 can extend beyond a surface 42a of the first end 42. This facilitates cleaning the surface 54.

The septum 52 has a generally cylindrical shape. The septum 52 can be formed of a latex or synthetic rubber material. Alternately, the septum can be formed of a thermoplastic elastomer. The material used for the septum 52 should be non-toxic and sterilizable such as by means of radiation, steam or Ethylene Oxide.

Because the septum 52 is generally cylindrical in shape, it can be die-cut from a sheet, cut from an extruded rod or molded. The septum 52 can have an exemplary diameter on the order of .30 inches (0.762 centimeters). The height of the septum 52 can be, for

example, on the order of .125 inches (.3175 centimeters).

The first end 42 is also formed with a tapered interior surface 60 which terminates in an annular channel 62. The tapered interior surface 60 has a taper in a range of 5 degrees to 20 degrees. Preferably, the taper will be on the order of 12 degrees. With the indicated size of the above noted exemplary septum 52 and a 12 degree taper, diametric resealing compression of the septum 52 adjacent the channel 62 is on the order of 10%.

The channel 62 is bounded in part by a septum supporting ridge 62a. The channel 62 can typically have a depth in a range of .050~.070 inches (.127~.1778 centimeters).

A peripheral surface 64 of the septum 52 slidably engages the tapered interior surface 60 as the septum 52 slides into the first end 42. The annular channel 62 which underlies the interior peripheral surface 56 of the septum 52 is provided to permit the septum 52 to deform when a blunt cannula is inserted through an opening 66 therein.

The housing 40 is also formed with a fluid flow path 68 such that fluids injected via a blunt cannula inserted through the resealable opening 66 can flow into the catheter 36 for delivery to hand H of the patient.

The swaged end members 58 apply axial forces to the septum 52 thereby creating the domed exterior peripheral surface 54. The axial forces applied by the end members 58 slightly deform the regions 52a and 52b. In contradistinction, the tapered internal surface 60 applies radially directed forces to the septum 52, thereby forcing the opening 66 into a resealed condition.

In an alternate embodiment, the surface 52 could be formed as a flat, as opposed to a domed, surface.

Once the injection site 34 is lockingly engaged with the catheter 36, a sealed system is formed through which fluids can be infused into the catheter 36. The resealable septum 52 closes the fluid flow path 68.

Figures 4A and 4B illustrate in combination the injection site 34, a blunt shielded cannula 80 and a syringe of a conventional type 82. The syringe 82, as is well known, can be formed with a cylindrical hollow end 84 which carries a male luer-type twist lock thread 86. A hollow centrally located cylindrical fluid flow member 88 is in fluid flow communication with an interior region 90 of the syringe 82.

The shielded blunt cannula 80 carries at a first end 92 a female luer twist-lock flange 94. The flange 94 will slidably engage the threads 86 of the end 84. Hence, the shielded blunt cannula 80 can be locked to the syringe 82 forming a closed fluid flow pathway. The shielded cannula 80 could alternately be formed fixedly attached to the syringe 82.

The shielded blunt cannula 80 carries a cylindrical hollow protective shield 96 which surrounds a centrally located hollow, elongated cylindrical blunt piercing member 98. The cylindrical blunt piercing member 98 has a total length on the order of three times the thickness of the septum 52 in order to ensure complete penetration. The cylindrical blunt piercing member 98 has a diameter on the order of 1/3 the diameter of the septum 52. The shield 96 is desirable and useful for maintaining the piercing member 98 in an aseptic condition by preventing touch contamination prior to the shielded cannula 80 engaging the pre-slit septum 52. Also, the shield helps to align the piercing member with the pre-slit septum.

The cylindrical blunt piercing member 98 can slidably engage the pre-slit septum 52, best illustrated in Figure 4B, thereby extending through the preformed opening 66 therein. As illustrated in Figure 4B, when

the piercing member 98 slidably engages and pierces the septum 52, the region 52a deforms by expanding into and filling, at least in part, the annular channel 62.

The deformation facilitates insertion of the piercing member 98 through the slit 66. Subsequent to the piercing member 98 slidably engaging the injection site 34, the interior region 90 of the syringe 82 is in fluid flow communication with the flow path 68 of the injection site 34 via flow paths 88a and 98a respectively of the syringe and the blunt piercing member 98.

In this engagement condition, the septum 52 seals completely around the piercing member 98. Hence, exterior gases, liquids or airborne matter will be excluded from the channel 68.

Subsequent to infusing fluid from the syringe 82 into the fluid flow pathway 68, hence into the catheter 36 and the hand H of the patient, the syringe 82 with lockingly engaged shielded cannula 80 can be slidably withdrawn from the injection site 34. Subsequent to this withdrawal, the septum 52 reseals the opening 66 therein.

The opening 66 will repeatedly reseal, when the piercing member 98 is removed, provided that the pressure (in the septum 52 of the opening 66) created by interaction of the septum material properties and compression supplied by the housing exceeds the pressure challenge of the fluid contained within. Blunt cannula do not haphazardly core, lacerate, or otherwise damage the sealing interface 66 as conventional needles do, thereby allowing repeatable resealability. However, septum material properties, thickness, and compression allow resealability for a finite number of conventional needle insertions. The combination injection site 34 and catheter 36 then return to its pre-infusion, sealed condition.

Figures 5A and 5B illustrate the pre-slit injection site 34 used in combination with a blunt

cannula 80a. The cannula 80a includes a hollow body portion 92a with a Luer flange 94a, a piercing member 98a, and manually operable elongated locking members 100a and 100b. Alternately, a tubing member could be affixed to the hollow body portion 92.

Curved end regions 100c of the members 100a and 100b slidably engage the second end 44 of the housing 40 when the piercing member 98a of the blunt cannula 80a has been forced through the pre-formed opening 66, best illustrated in Figure 5B. The embodiment illustrated in Figures 5A and 5B has the advantage that the infusion cannula 80a cannot accidentally disengage from the pre-slit septum 34 during the fluid infusion process. It will be understood that while spring-like deflecting members 100a and 100b are illustrated in Figures 5A and 5B that other forms of locking members are within the spirit and scope of the present invention.

Figure 6 illustrates an alternate pre-slit injection site 34a. A tubing member 102 can be fixedly attached to the cylindrical hollow fluid flow member 46. The embodiment 34a of Figure 6 utilizes the same structure for the septum 52 including the tapered surface 60 and the underlying annular channel 62 as does the embodiment 34 in Figure 3. The shielded cannula 80 can be utilized with the injection site 34a as previously described.

In the event that it is desirable to infuse solution from a container 104 with a connectional port 106, a fluid administration set 110 of a conventional variety may be utilized. The set 110 includes a spike connector 112 at a first end. The spike connector 112 is designed to pierce the port 106 of the container 104. The set 110 can also carry a slidably engageable connector 114 of a known type at a second end. As illustrated in Figure 7, the connector 114 can slidably engage the hollow cylindrical member 92 of the shielded cannula 80, thereby placing the interior fluid of the

container 104 into fluid communication with the tubing member 102.

Figure 8 illustrates yet another alternate 80b to the shielded cannula 80. The piercing member 98 carries a tubing member 118 fixedly attached thereto. The tubing member 118 could be coupled at a second end to a container such as the container 104.

The present pre-slit injection site can be directly affixed to a container 120 as illustrated in Figure 9. The container 120 includes a rigid hollow cylindrical access port 122 affixed thereto. The access port 122 includes a fluid flow channel 124 in fluid flow communication with the interior of the container 120. Sealingly affixed to the port 122 is a pre-slit injection site 126.

The site 126 includes a cylindrical housing 128 which carries at a first end 130 a septum 132 with a slit 134 formed therein. The first end 130 has been swaged to form an annular U-shaped retaining member 136. The retaining member 136 in turn forms a domed exterior peripheral surface 138 on the septum 132.

The first end 130 also includes a tapered interior force applying surface 140 and an annular channel 142 underlying the septum 132. As discussed previously, the channel 142 provides a space into which the septum 132 can deform when a blunt cannula is forced through the resealable opening 134.

Further, as illustrated in Figure 9, the injection site 126 can be covered by a removable cover 146 of a type used with the conventional port 106 of the bag 104.

While the bag 120 is illustrated formed with two ports, the conventional pierceable port 106 and the pre-slit injection site 126, it will be understood that as an alternate (Figure 10), a container 150 could be formed which includes only the pre-slit injection port 126. The removable cover 146 could be used in combination with the container 150.

As illustrated in Figure 11, the pre-slit injection site 126 can be utilized for the purpose of injecting fluid from the syringe 82, coupled to the shielded cannula 80, into the container 150. When so utilized, the blunt piercing member 98 is used to place the interior fluid containing region 90 of the syringe into fluid flow communication with the interior of the container 150.

Figures 12 and 13 illustrate a fluid flow coupling system 151 having as a first element a pre-slit injection site 126a. The site 126a is the same as the site 126 except for a plurality of exterior threads 153 formed on an exterior peripheral surface 155 of the housing 128a. A second element of the coupling system 151 is a shielded blunt cannula 157.

The shielded blunt cannula 157 is sealingly affixed to a flexible tubing member 159 by means of a proximal hollow cylindrical member 161. The member 161 extends into a hollow cylindrical shield 163 to form a blunt piercing member 165.

The shield 163 carries, on an interior peripheral surface, a set of coupling threads 165. The threads 165 match the threads 153.

The two connector elements 126a and 157 slidably engage one another when the shielded cannula 157 moves in an axial direction 167 toward the injection site 126a. The blunt piercing member 165 penetrates the septum 132a.

The coupling member 157 can then be rotated in a direction 169 such the interior set of threads 165 carried thereon engages the exterior set of threads 153. As a result, the two coupling members 126a and 157 are lockingly engaged together with the insertion member 165 extending through the opening 134a in the septum 132a. Hence, fluids can flow from the container 150a via the connector system 126a and 157 through the tubing member 159 to the recipient.

Injection sites of the type described above

are also usable in connection with other fluid flow coupling components. For example, with respect to Figure 14, a pre-slit injection site 160 of the type described above can be used in combination with a spike connector 162 of a conventional variety. Spike connectors such as the spike connector 162 can be used to pierce conventional ports such as the port 106 of the container 104 (Figure 6). When the spike connector 162 is so used, the pre-slit injection site 160 can then be utilized for the purpose of coupling to other fluid administration sets.

The injection site 160 illustrates an alternate form of swaging the first end 42c for the purpose of retaining the septum 52c therein. The first end 42c can be swaged so as to form an annularly shaped, spiral, spring-like member 164. The member 164 has a free end 164a which engages the exterior dome-shaped peripheral surface 54c of the septum 52c. The spiral, spring-like swaged member 164 will tend to uncoil, thereby continuously applying axial force to the septum 52c and maintaining the domed exterior peripheral surface 54c.

In yet another alternate, Figure 15 illustrates a pre-slit injection site 166 formed in a Y-junction member 168. The Y-junction member 168 is fixedly attached to first and second tubing members 170 and 172 respectively.

As an alternate to forming the slit 66d completely through the septum 52d, as illustrated in Figure 16, a slit 66e can be formed only partly through the septum 52e. Such a structure has the further advantage that, until used for the first time, the septum 52e is completely sealed.

The septum 52e can be formed in two parts. One part can have a slit, such as the slit 66e, extending entirely therethrough. A second part can be formed without a slit. These two parts can be located adjacent one another in the first end 42e of the

injection site.

The slit 66e may be longer on the top of the septum than the bottom. this feature aids blunt cannula alignment with the slit upon insertion, and aids resealability by minimizing the critical slit sealing interface area.

In accordance with the present invention, the slit could have a length with a range on the order of .03 inches (.0762 centimeters) to .150 inches (.381 centimeters). Preferably, a slit length on the order of .07 inches (.1778 centimeters) will be used in combination with a blunt cannula having a diameter on the order of .1 inches (.254 centimeters).

When initially used, the blunt cannula piercing member, such as the member 98, will be forced through the slit 66a. The lower peripheral surface 56e will then be punctured, providing access for the blunt cannula piercing member 98 into the fluid flow pathway 68e.

Pre-slit injection sites of the type described above can be utilized in combination with burette solution administration sets. One such set 176 is illustrated in Figure 17. The set 176 includes a pre-slit injection site 178 of the type described above. The injection site 178 is affixed to an exterior planar surface 180 of the burette 182. A removable cover 184 can be used to maintain the injection site 178 in an aseptic condition until blunt cannula 186 or 188 is inserted therethrough.

Figures 19 through 23 disclose a method of making a pre-slit injection site in accordance with the present invention. In a first step, a housing 200 is provided. The housing 200 has an interior tapered surface 202 at a first end 202a thereof. The interior peripheral surface terminates in an annular channel 204. A cylindrical septum 206 can be provided adjacent the end 200a.

In a second step, the septum 206 can be forced

into the end 202a of the housing 200 and slightly deformed by the tapered peripheral surface 202 using an axially moving die 210. When positioned by the die 210, the septum 206 is located adjacent an internal annular right 212 which bounds the annular channel 204.

In a third step, a second die 214 can be utilized to swage the end 200a into spiral-shaped, spring-like members 200b which apply axially directed forces against an exterior peripheral surface 206a of the septum 206. The axially directed forces form the flat surface 206a into a domed exterior peripheral surface 206b as illustrated in Figure 23.

Simultaneously, with swaging the end members 200a so as to lock the septum 206 into the housing 200 and to form the domed exterior peripheral surface 206b, a knife 216 can be utilized to form a slit in the septum 206. Alternatively, the slit may be cut by a separate die in a separate step. If the septum 206 is formed as an extrusion, the slit can be created during the extrusion process. If the septum 206 is formed by stamping from a rubber sheet, the slit can be cut during the stamping process. If the septum 206 is formed by compression molding, the slit can be cut during the trimming process.

In order to extrude the slit into rod, a flat pin extrusion bushing can be used. A trailing ribbon may be attached to the bushing. The ribbon would prevent curing material across the slit. The ribbon or wire could be placed in the rod core and later stripped out leaving a slit. An inert substance, such as silicone oil, could be coextruded in the center of the rod to prevent curing across the slit and provide lubrication and a visible target for cannula insertion.

Figures 24 and 25 illustrate alternate swaging steps wherein a die 220 moving axially toward the housing 200 swages the end region 200a so as to form an annular U-shaped region 200c and the exterior domed peripheral surface 206c.

The dies 214 or 220 can be formed with various alternate shaped swaging surfaces 224, as illustrated in Figure 26, depending on the precise shape of the end swage which is desired. It will be understood that all such variations in the swaging operation are within the spirit and scope of the present invention.

The injection site configuration need not be limited to the configurations depicted in Figures 3 through 5B, 9, and 12 through 16. Rather, several configurations could be constructed without departing from the scope of this invention. Any such configuration would provide a flexible pre-slit sealing member captured in a chousing which provides compression to create a seal against pressure and a void region to accommodate deformed portions of the sealing member material only when the material is deformed or displaced by a blunt cannula piercing member. One such possible configuration is depicted in Figures 27 and 28.

Figures 29 and 30 illustrate a tapered cannula structure 250 which is an alternate to the tapered cannula 98. The cannula 250 includes a proximal end 252 with an interior region 254. The region 254 is in part bounded by an internal peripheral wall 256 which is formed with a standard Luer taper. The tapered cannula 250 can be formed with a Luer-type coupling flange 257 at the proximal end so as to be releasably connectable to the syringe 82 as was the tapered cannula 98 previously discussed.

Extending from the proximal end 252 is a cylindrical tube having a cylindrical mid-region 258 and a distal end member 260. The member 260 has a generally elongated, cylindrical shape with an exterior side wall 262. A centrally located, cylindrical, internal fluid flow path 264 extends through the distal end member 260 and mid-region 258 in fluid flow communication with the interior region 254.

The distal end of the end member 260 has a tapered exterior surface 266. The tapered exterior

surface 266 minimizes insertion force as the cannula 250 is being forced through a slit of a septum, such as the slit 66 in the septum 52. The angle of taper of the surface 266 is preferably in a range between 1 to 15 degrees.

The member 260 is also provided with a plurality of elongated grooves 268. The grooves 268 in the exterior wall of the member 260 decrease the surface area of contact at the cannula/septum interface during insertion of the cannula into the injection site 34. This reduced exterior contact surface area decreases the frictional component of the insertion force.

In one embodiment, the tapered blunt cannula 250 may have overall insertion length, corresponding to combined axial lengths of mid-region 258 and end member 260, on the order of 0.375 inches (.9525 centimeters).

An alternate cannula structure 280 is illustrated in Figures 31, 32 and 33. The cannula structure 280 includes a proximal end region 282 corresponding to the end region 252 of the cannula 250. The region 282 includes a Luer flange 283. The cannula 280 also includes a central, elongated, cylindrical region 288.

The central region 288 carries at a distal end thereof an elongated cylindrical end member 290. The member 290 includes an exterior, peripheral, cylindrical surface 292 (Figure 31). The surface 292 is interrupted by a plurality of spaced-apart, elongated slots or apertures 294. The slots 294 are defined by first and second spaced-apart, elongated, parallel side surfaces 294a and 294b. Each of the slots terminates in an end surface 294c at the central region 288.

A fluid flow path 294d extends through the cannula 280. The flow path 294d is in fluid flow communication with the slots 294.

Between the slots 294, at a distal end of the region 290, the exterior surface 292 terminates in tapered end regions 298 to facilitate insertion of the

cannula into a pre-slit injection site. The slots 294 themselves also function to decrease the surfac contact area, and this further minimizes the insertion force.

The slots 294 are oriented substantially 90 degrees apart around a longitudinal axis 300. The slots 294 increase the internal flow path cross-section. This increases the fluid flow rate.

The slots 294 also provide for enhanced dispersion characteristics owing to the fluid flowing radially out through the slots 294. This radial flow, effecting as change in fluid flow direction of about 90 degrees, promotes flushing and dispersion of fluid through the injection site 34.

Another embodiment of a blunt cannula 310 is illustrated in Figures 34 through 37. The cannula 310 is formed with an enlarged proximal connection region 312 corresponding to the region 252 of the cannula 250. The region 312 includes a Luer flange 313 and a central fluid flow region 314.

An intermediate, cylindrical region 318 extends from the proximal connection region 312. The cylindrical intermediate region 318 includes a fluid flow path 320 in communication with the fluid flow region 314.

The end region 324 extends from the region 318 and includes a first cylindrical portion 326 into which the fluid flow path 320 extends. The region 326 terminates in a tapered exterior surface 328. The tapered exterior surface 328 merges with a centrally located lead post or guide post 330. The lead post 330 terminates in a hemispherical end surface 332.

The lead post 330 helps locate the septum slit 66 prior to insertion and facilitates penetration of the septum slit 66 by the cannula. The lead post 330 facilitates insertion by providing a very low insertion force at the beginning of the insertion step as the cannula is pushed through the slit, such as the slit 66.

In a preferred mbodiment, the guide post 330

can have a length on the order of 0.060 inches (.1524 centimeters) and a diameter on the order of 0.050 inches (.127 centimeters).

The end region 318 includes a novel structure for increasing the flow rate and enhancing dispersion characteristics. In particular, the region 318 includes three radially oriented slots 338. Each slot 338 has sides 339a and 339b which each lie along a radius of the cylindrical portion 326 as best illustrated in Figure 37. The fluid flowing through the cannula 310 undergoes a change in direction (of up to about 90 degrees relative to the cannula center line 337) in the slots 338. This change in direction increases fluid dispersion. Further, since the slots 338 open radially, fluid flow can be maintained even if the end surface 332 of the cannula is pushed up against any material in the system in which the cannula is inserted.

Another embodiment of the tapered cannula of the present invention is illustrated in Figures 38 through 40 and is designated generally therein by reference numeral 340. The cannula 340 includes a proximal end 342 which can include a Luer coupling flange 344 for cooperating with a suitable mating structure on a syringe. The proximal end 342 also defines an interior region 346.

Extending from the proximal end 342 is a generally cylindrical mid-region 348. Extending from the mid-region 348 is an end member or region 350 which includes a tapered surface 352.

The distal end of the end region 352 terminates in a blunt, arcuate end surface 356. Defined within the mid-region 348 and end region 350 is an internal fluid flow channel 354 which communicates with the interior region 346. Fluid discharges from the flow channel 354 via grooves or apertures 358 in the end region 350. The change in direction of the fluid flow as the fluid passes from the interior channel 354 through the apertures 358 improves fluid dispersion with

respect to mixing or flushing in the system downstream of the cannula (e.g., the injection site, drug vial, etc.). The apertures 358 may also function to increase withdrawal force or tug resistance.

Moreover, since the fluid passes radially out through the apertures 358, fluid flow through the cannula 340 can be maintained even when the distal end surface 356 of the cannula is bottomed out or pushed against any material in the system in which the cannula is inserted.

The structure of the cannula 340 is adapted to be constructed with a minimal lead post length (i.e., the portion of the cannula distal end between the end surface 356 and the interior flow channel 354). Further, the design accommodates the use of a minimal tip diameter, minimal taper angle, and minimal cannula diameter. The minimization of these parameters results in a decrease in the peak insertion force required to properly install the cannula in the injection site.

Preferably, the total cross-sectional flow area through the three apertures 358 is about three times the cross-sectional flow area of the interior channel 354. This enhances the flow rate capability compared with a simple open ended cylindrical flow channel of equal length.

The design of the cannula 340 also is effective in reducing or limiting "kick back" or recoil of the cannula after insertion. The resilient material of the septum in an injection site can subject the cannula to forces tending to push the cannula back out of the septum. The kick back forces on the cannula 340 are minimized by the provision of the generally cylindrical mid-region 348.

Another embodiment of the cannula of the present invention is illustrated in Figures 41 and 42 wherein the cannula embodiment is designated generally therein by the reference numeral 360. The cannula 360 includes a proximal end 362 defining an interior region

364 and having a Luer flange 366 for connection to a suitable mating engaging structure.

A generally cylindrical mid-region 366 extends from the proximal end 362, and an end region 368 extends from the mid-region 366. As with the previous embodiment of the cannula 340 illustrated in Figures 38 through 40, the embodiment of the cannula 360 minimizes kick back or recoil owing to the provision of a substantially cylindrical mid-region 366. This design also increases withdrawal or tug resistance.

A generally cylindrical internal flow channel 370 extends through the end region 368 and mid-region 366 in communication with the interior region 364 of the proximal end region 362. The end region 368 is provided with a tapered surface 372. The design permits the use of a very small taper to minimize the insertion force.

Further, the design permits the cannula 360 to be constructed with a small tip diameter, small taper angle, and small cannula diameter so as to reduce the peak insertion force.

Another embodiment of the cannula of the present invention is illustrated in Figures 43 through 44 and is designated generally therein by reference numberal 380. The cannula 380 includes a proximal end 382 with a Luer flange 384. An interior fluid flow region 386 is defined on the interior of the proximal end 382.

Extending from the proximal end 382 is a mid-region 388. A distal end region 390 extends from the mid-region 388. An internal fluid flow channel or path 392 extends through the end region 390 and mid-region 388, and is in communication with the interior flow region 386.

The end region 390 has an exterior tapered surface 394. This facilitates insertion of the cannula into the injection site. In contrast, the mid-region 388 is generally cylindrical so as to minimize kick back and increase the withdrawal force or tug resistance.

Further, to provid even gr ater withdrawal force, the mid-region 388 includes an annular barb 396. The barb 396 has a sufficient radius so as to preclude damage to the septum of the injection site and so as to accommodate molding in a straight draw tool. The maximum diameter of the annular barb 396 may typically be on the order of 0.02 inches (.0508 centimeters) greater than the diameter of the cylindrical mid-region 388. Although the barb 396 functions to prevent inadvertent removal of the cannula 380 from the septum of the injection site, removal of the cannula 380 can still be achieved by entering a sufficiently great axially directed removal force on the cannula 380.

Still another embodiment is illustrated in Figure 45 which includes a blunt tapered cannula insertion member 400 for insertion into a pre-slit injection site, the cannula 400 having a distal end region 402 with a tapered exterior surface which in the preferred embodiment is an approximately 8 degrees taper. The defined aperture 404 for fluid flow is disposed at the end 406 of the distal end region 402. The end 406 includes a radiused tip defined by a radius of approximately 0.01 inch (.025 centimeters). The radiused tip reduces insertion force, assists in locating the slit in the injection site and in addition has the practical advantage of facilitating complete filling of the cannula mold cavity.

The tapered surface of the distal end region 402 has an axial length of approximately 0.10 inch in the preferred embodiment. Adjacent to the tapered distal end region is a generally cylindrical region 408 for entering into the injection site behind the distal end region 402, thereby reducing kick back during insertion. The generally cylindrical region 408 has a small draft angle such as about one-half degree.

The force required to insert any of the above-discussed embodiments of the blunt tapered cannula into the septum of the injection site depends upon a number

factors: friction at the cannula/septum interface, cannula diameter, cannula taper angle, and degree of septum compression. The cannula/septum interface friction is, in turn, dependent upon lubrication, if any, material properties, and surface finish. It will be understood that the friction at the cannula/septum interface can be reduced by providing a smoother surface finish on the cannula (e.g., by sand blasting the cannula exterior surface) or by molding the cannula so as to produce a matte finish. Conventional lubricants can also be used to further reduce the friction and thereby lower the insertion force required.

In the embodiments of the cannulae described herein, the mid-region and the tapered distal end region may be alternatively characterized as together forming at least one tube defining a fluid flow path therein with the tube having a distal end region for penetrating the injection site.

In preferred contemplated embodiments, the exterior surface of the distal end region may have a taper angle as small as between 1 and 15 degrees.

Further, a locking means, such as the locking arms 100a and 100b discussed with reference to Figures 5A and 5B, may be provided on the cannula embodiments illustrated in Figures 29 through 44 to permit the cannulae to be releasably locked to the injection site.

The above described insertion members, usable as part of a blunt cannula, are preferably molded of a plastic formulation including silicone or other lubricant. The use of silicone or other lubricant increases the ease of insertion of that member into the pre-slit injection site.

From the foregoing, it will be observed that numerous variations and modifications may be effected without departing from the spirit and scope of the novel concept of the invention. It is to be understood that no limitation with respect to the specific apparatus illustrated herein is intended or should be inferred.

It is, of course, intended to cover by the appended claims all such modifications as fall within the scope of the claims.

What is Claimed is:

1. An easily wipeable injection site usable with a blunt cannula comprising:

a housing defining a fluid flow channelthere-through, said housing having a first and a second end; and

flexible means carried by said housing for sealing said first end, said means having a resealable opening therein and a curved exterior peripheral surface such that the blunt cannula can be sealingly inserted through said opening and placed in fluid flow communication with said flow path and such that the blunt cannula can be removed therefrom with said sealing means interacting with said housing so as to reseal said opening.

2. An injection site as in Claim 1 wherein said resealable opening extends at least partway through said sealing means.

3. An injection site as in Claim 1 wherein said resealable opening extends entirely through said sealing means.

4. An injection site as in Claim 1 with said first end of said housing defining a tapered interior surface, and with said sealing means including a cylindrical sealing member positioned in said first end adjacent said tapered interior surface, said tapered interior surface interacting with a peripheral surface of said sealing member so as to general resealing radial forces, directed inwardly toward a centerline of said flow channel, to urge said resealable opening into a closed condition.

5. An injection site as in Claim 4 with said radial resealing forces increasing from a first value adjacent to said exterior peripheral surface to a second, greater value displaced from said peripheral surface toward said second end.

6. An injection site as in Claim 4 wherein a region of said first end is deformed and directed against said exterior peripheral surface, thereby applying axially directed forces thereto and thereby forming said curved peripheral surface.

7. An injection site as in Claim 4 including an annular channel underlying said tapered surface to provide for deformation of said sealing means when the blunt cannula is inserted therethrough.

8. An injection site as in Claim 1 with said cannula carrying means for lockingly engaging said housing.

9. A coupling system for coupling first and second fluid flow members together comprising:

an injection site affixed to the first fluid flow members, said site including:

a housing with a fluid flow path therein;

sealing means carried by said housing with a resealable opening therein;

annular retaining means carried by said housing for retaining said sealing means therein;

means for applying radially directed forces to said sealing means, thereby urging said opening into a resealed condition; and

a blunt cannula affixed to the second fluid flow member with a fluid flow path therethrough for engaging and extending through said opening, thereby placing the two fluid flow members into sealed fluid flow communication.

10. The coupling system as in Claim 9, said blunt cannula further comprising locking means for lockingly engaging said housing when said cannula engages and extends through said opening.

11. A coupling system as in Claim 9 with said

blunt cannula carrying protective means.

12. A coupling system as in Claim 11 with said protective means formed as a cylindrical shield member.

13. A cannula insertion member for being inserted into a pre-slit injection site, said insertion member comprising:

at least one tube defining a fluid flow path therein, said tube having a distal end region for penetrating said injection site;

said tube defining at least one aperture in said distal end region through which fluid can flow to or from said fluid flow path; and

said tube including means for reducing the insertion force, said means including longitudinally oriented grooves in the exterior surface of said tube and a tapered surface on a least part of said distal end region.

14. An insertion member as in Claim 13 in which said tube is cylindrical and in which said grooves are positioned at 90 degree increments around the periphery of said tube.

15. An insertion member as in Claim 13 in which said tapered surface terminates at the distal end of said tube.

16. An insertion member as in Claim 13 in which said aperture is a circular opening at the distal end of said tube.

17. An insertion member as in Claim 13 in which each said groove includes an arcuate bottom surface.

18. A cannula insertion member for being inserted into a pre-slit injection site, said insertion member comprising:

at least one tube defining a fluid flow path

therein, said tube having a distal end region for penetrating said injection site;

said tube defining at least one aperture in said distal end region through which fluid can flow to or from said fluid flow path; and

said distal end region including a tapered exterior surface to facilitate insertion, said tube also including a generally cylindrical region extending from said tapered distal end region for entering into said injection site behind said distal end region and reducing kick back during insertion.

19. An insertion member as in Claim 18 in which said tapered distal end region has a length of approximately one-half the length of said generally cylindrical region.

20. An insertion member as in Claim 18 in which said insertion member includes an annular barb on the exterior surface of said tube at the junction of said cylindrical region and said tapered distal end region to increase tug resistance.

21. An insertion member as in Claim 1 in which said insertion member includes locking means for removably locking said member to said injection site.

22. An insertion member as in Claim 21 in which said insertion member includes locking means for removably locking said member to said injection site.

23. An insertion member as in Claim 22 in which said locking means includes an elongate, deflectable arm that is engageable with said injection site.

FIG_1
PRIOR ART

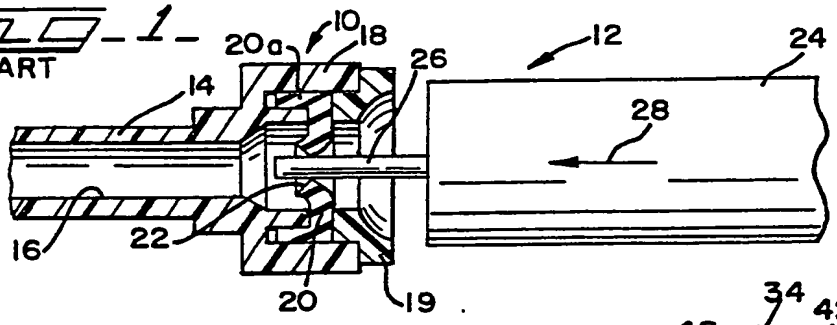


FIG_2A

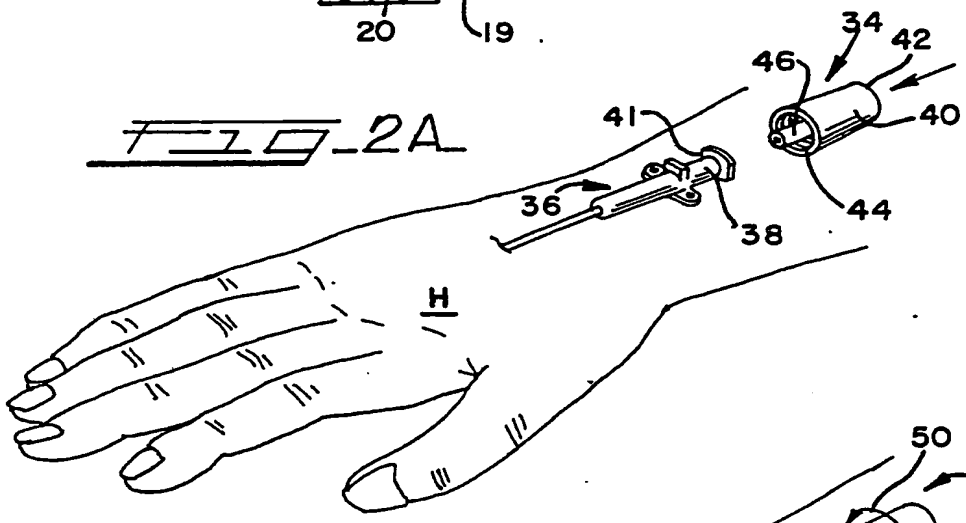


FIG_2B

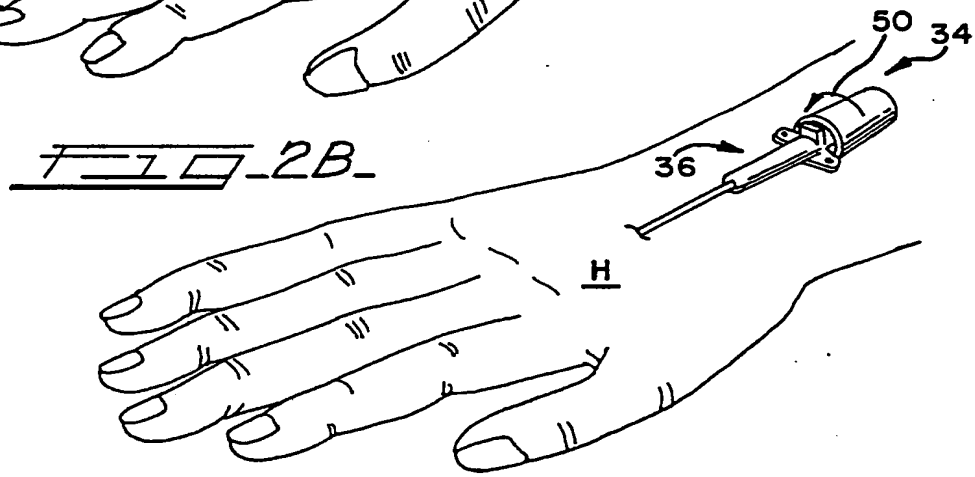


FIG_3

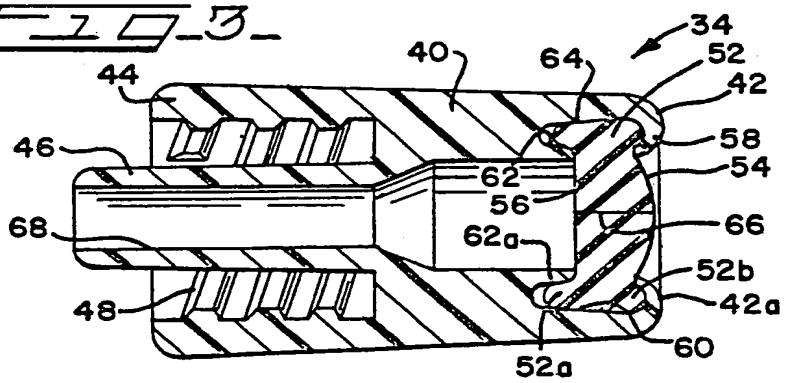


FIG_4A_

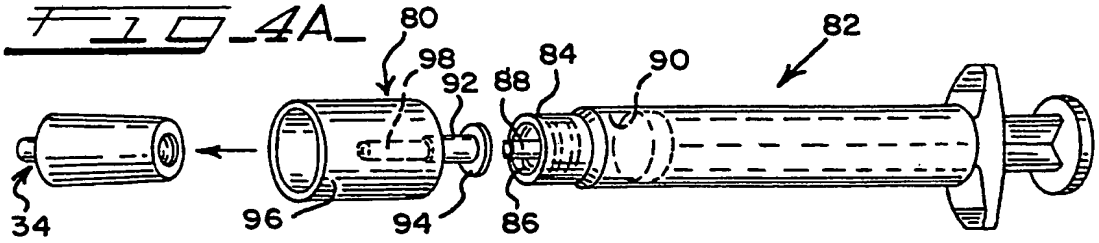


FIG_4B_

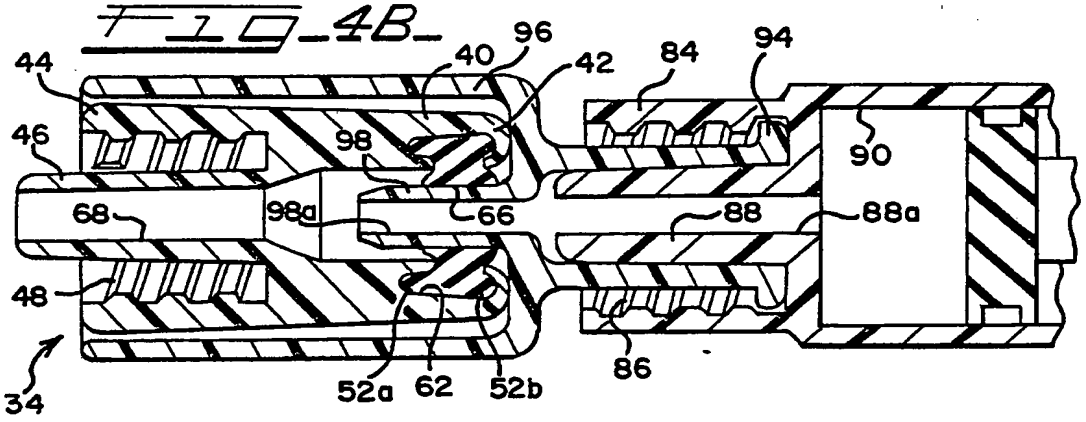


FIG_5A_

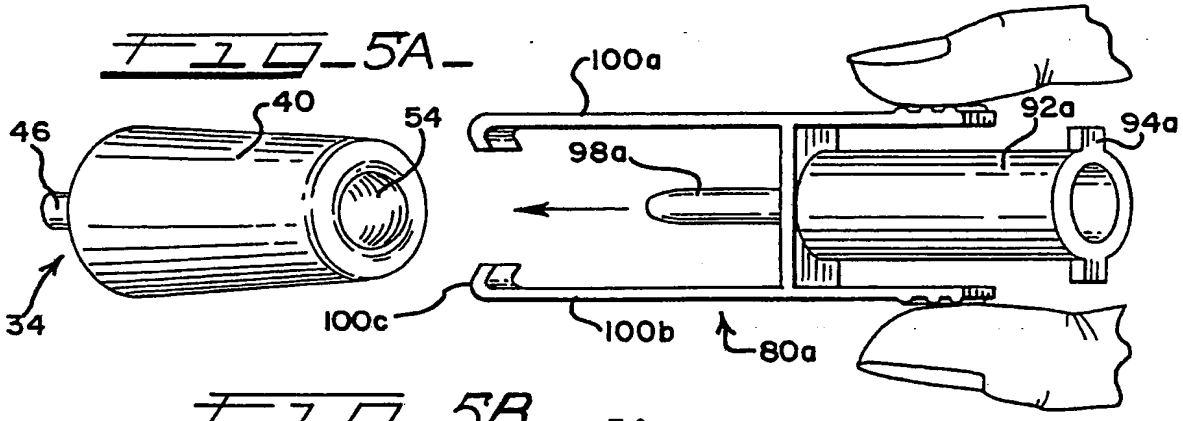


FIG_5B_

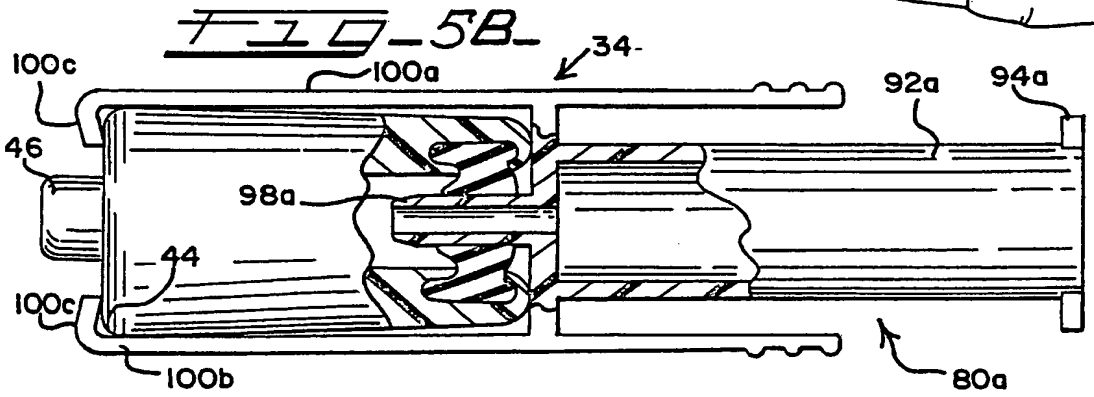


FIG-7

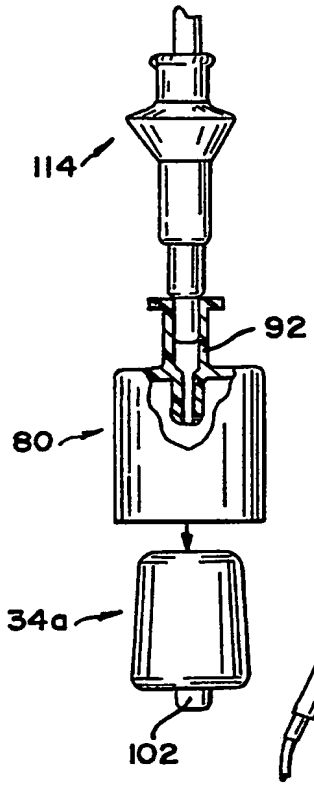
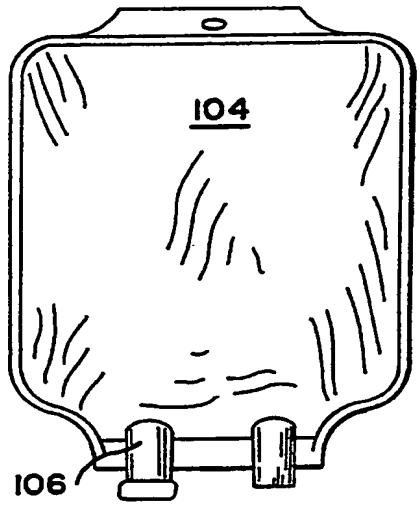


FIG-6



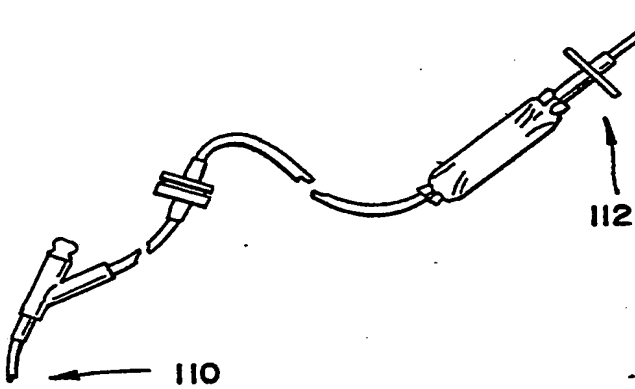
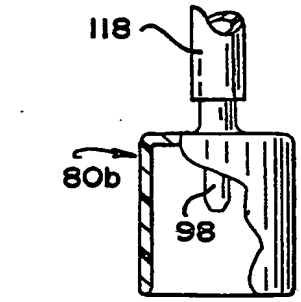


FIG-8



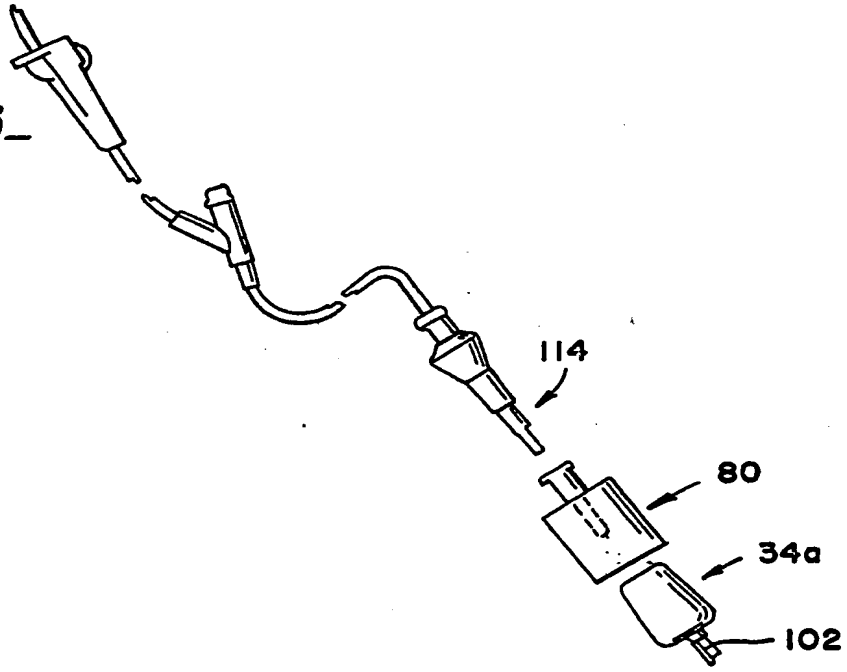
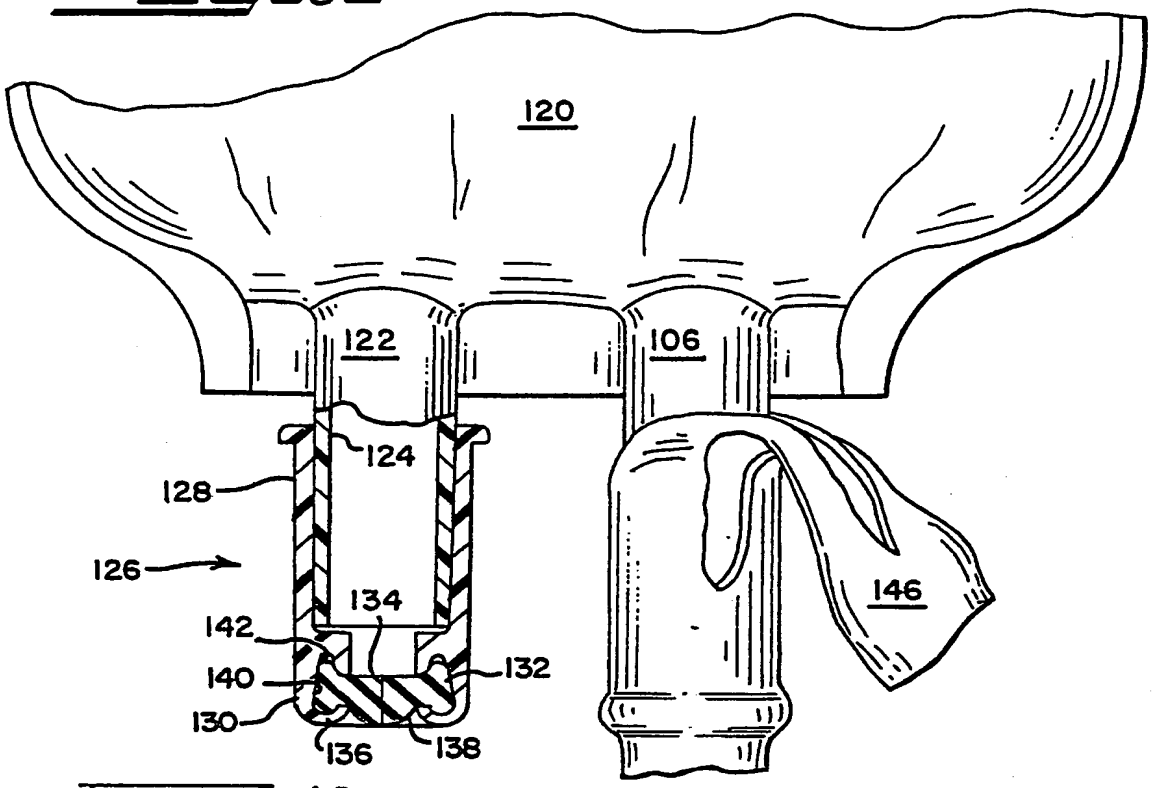


FIG-9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146

FIG-10

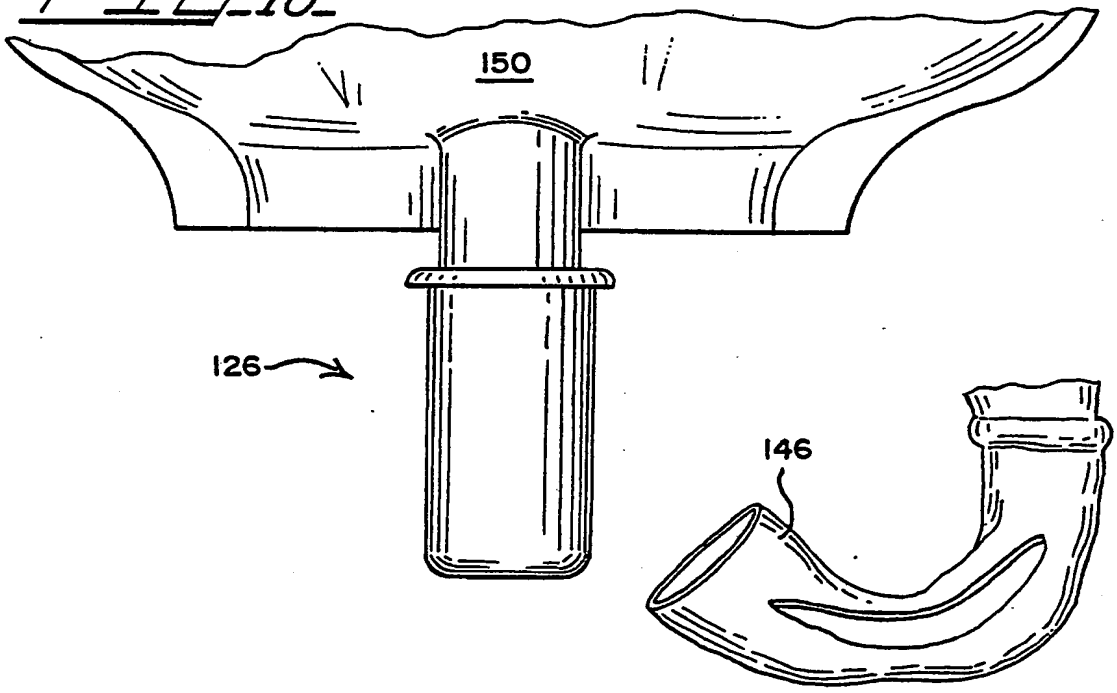
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FIG_11

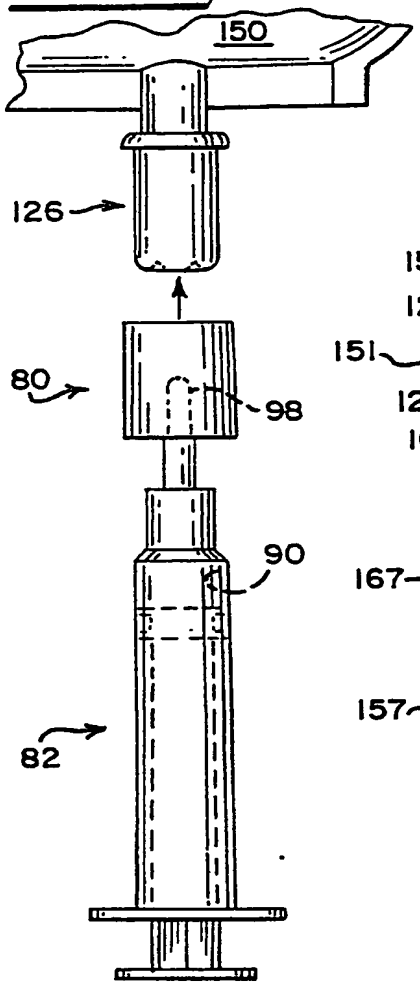


FIG_12

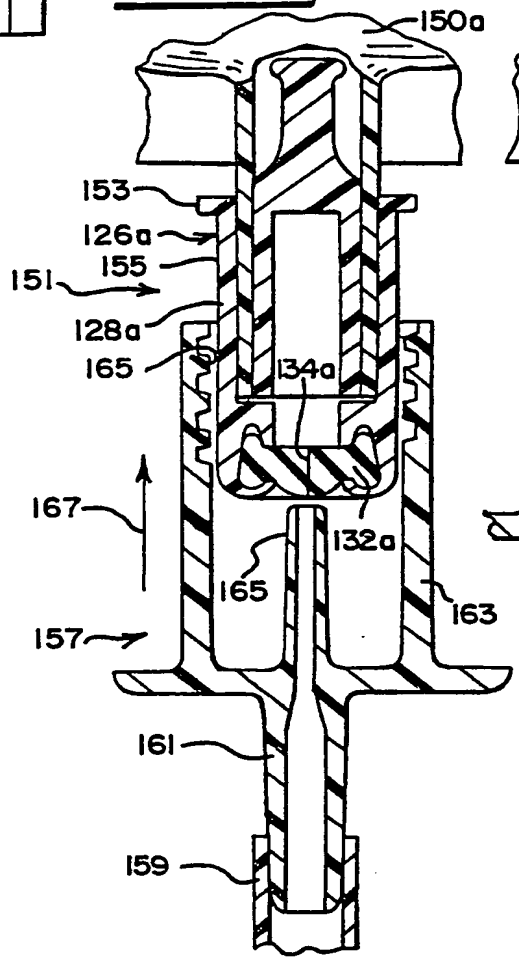


FIG_13

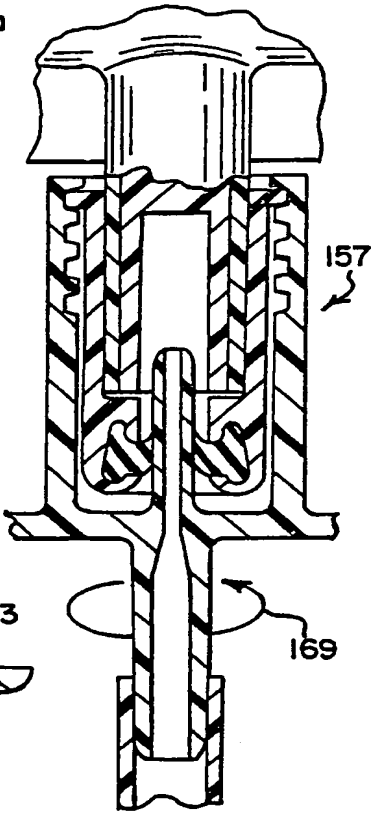


FIG_14

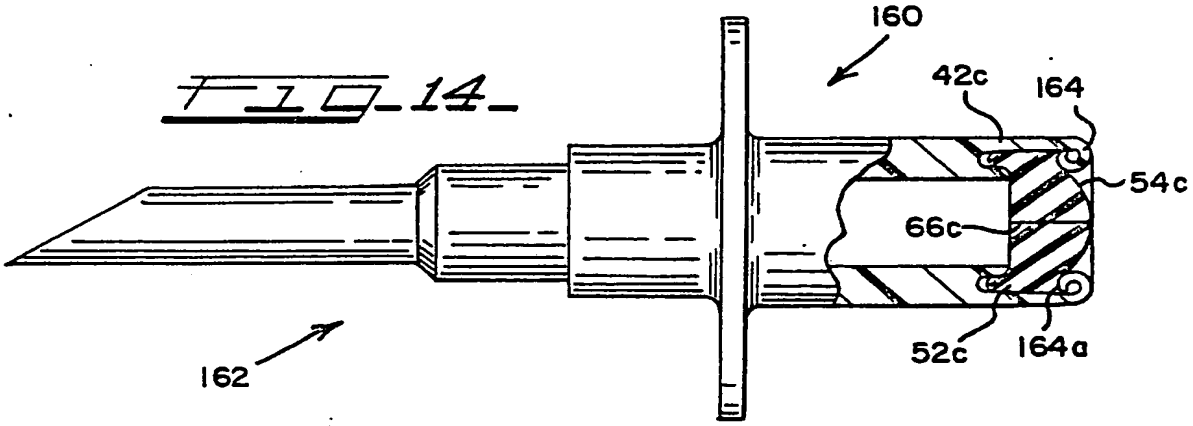


FIG_15

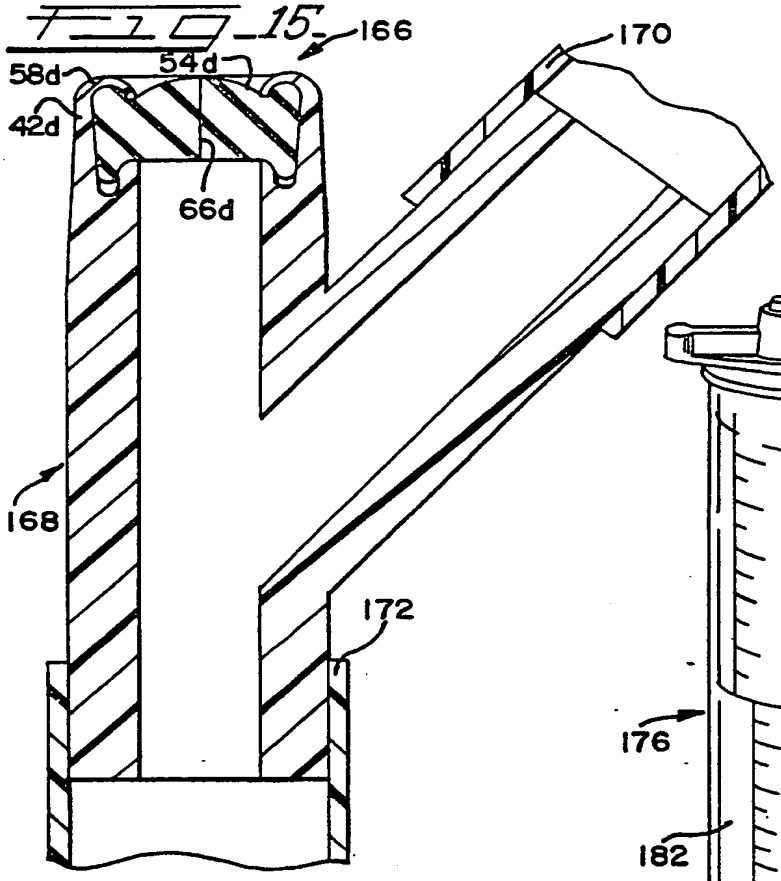
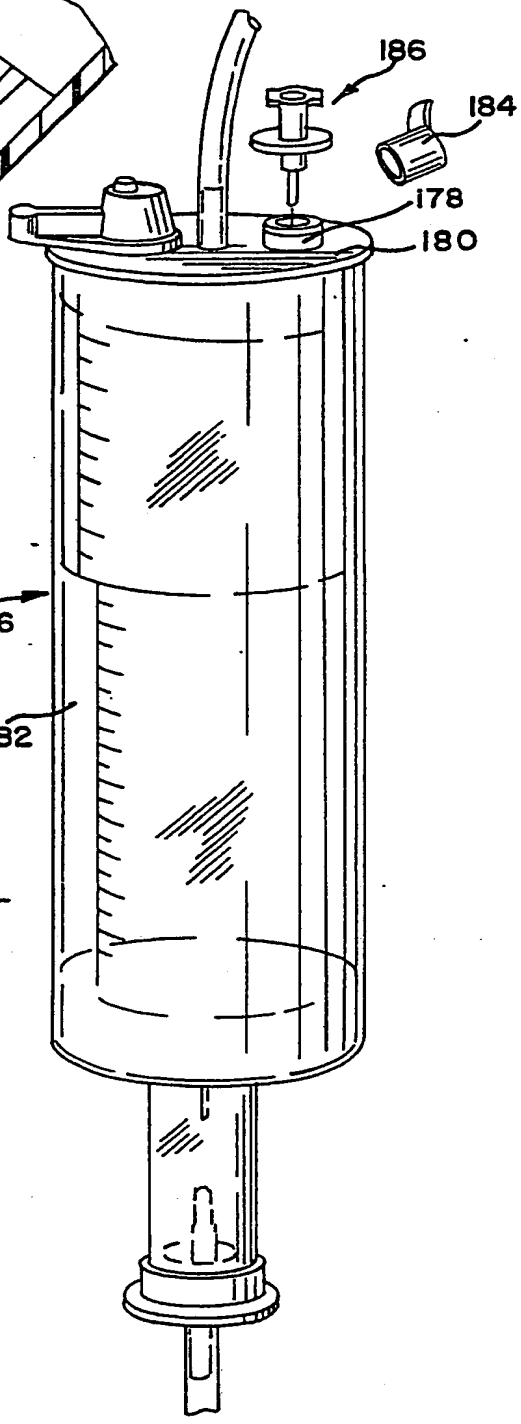


FIG_17



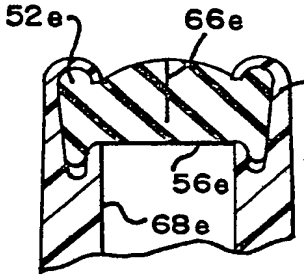


FIG_16

FIG_18

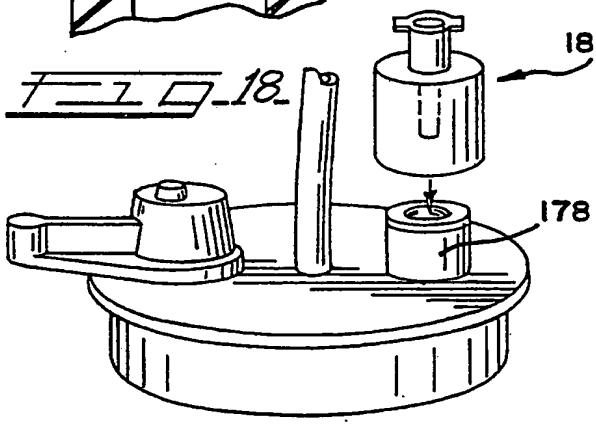


FIG. 19

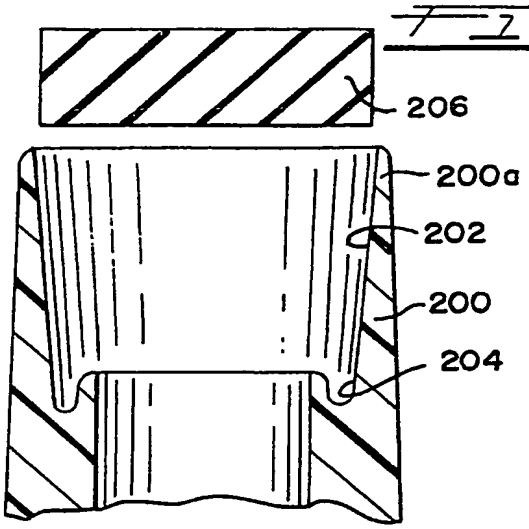


FIG. 20

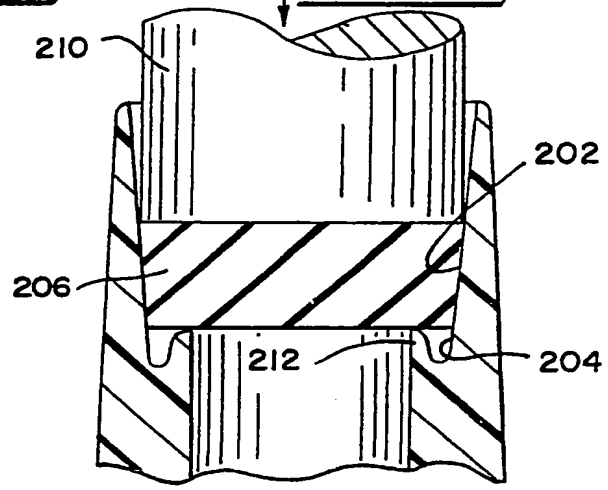


FIG. 21

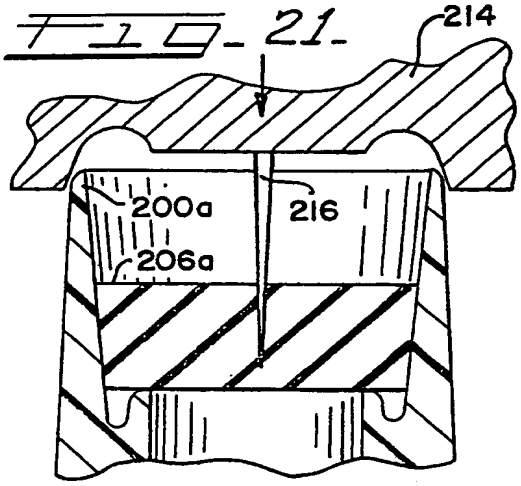


FIG. 22

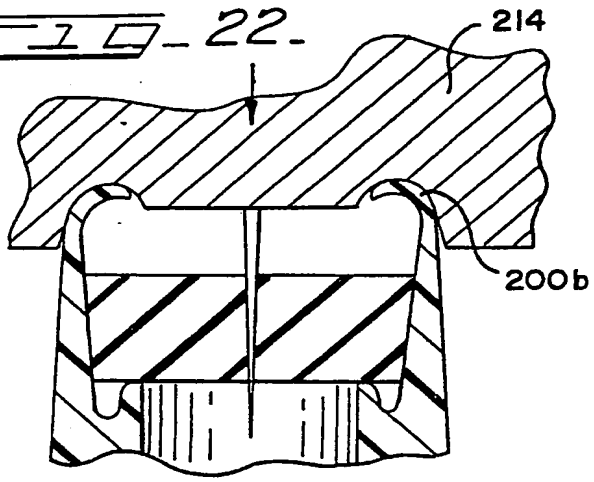


FIG. 23

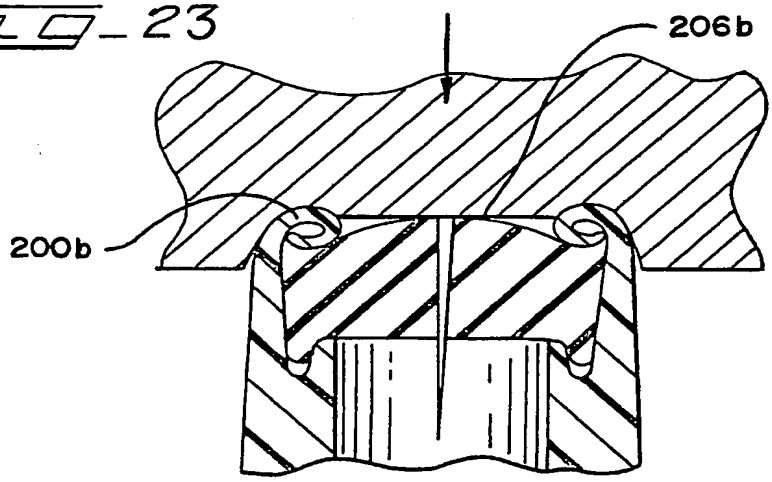


FIG. 24

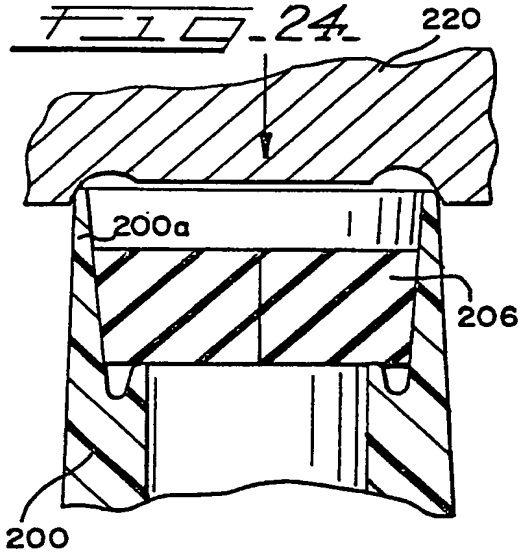


FIG. 25

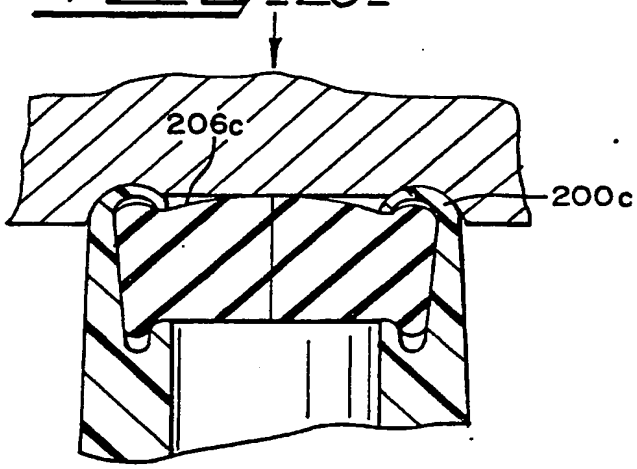


FIG. 26

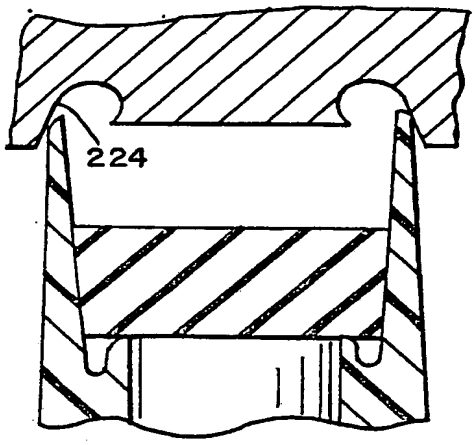


FIG. 27

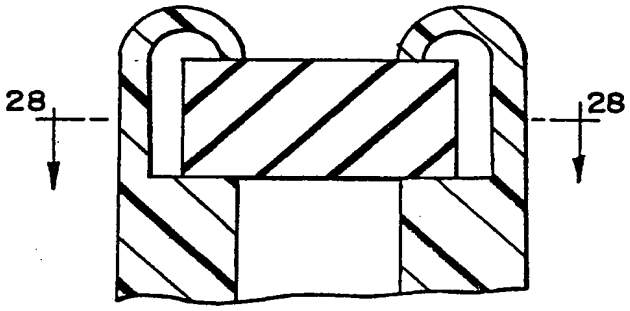


FIG. 28

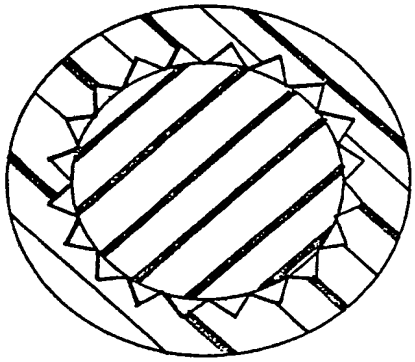


FIG_29

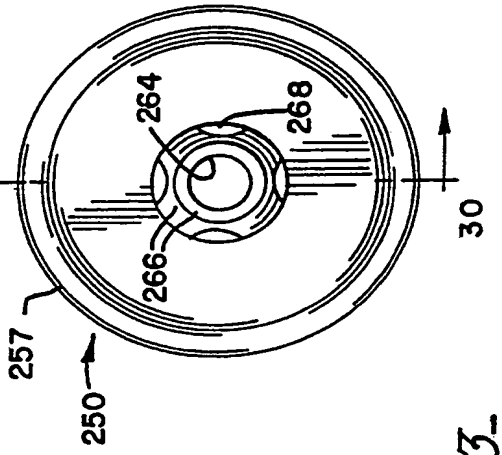


FIG_31

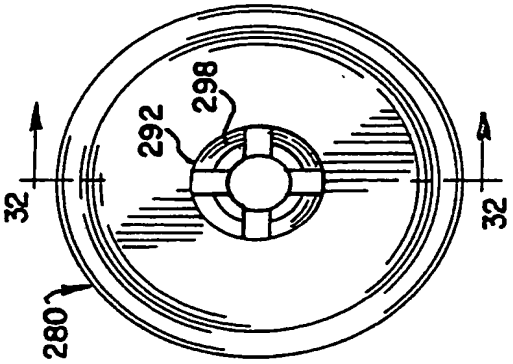


FIG_30

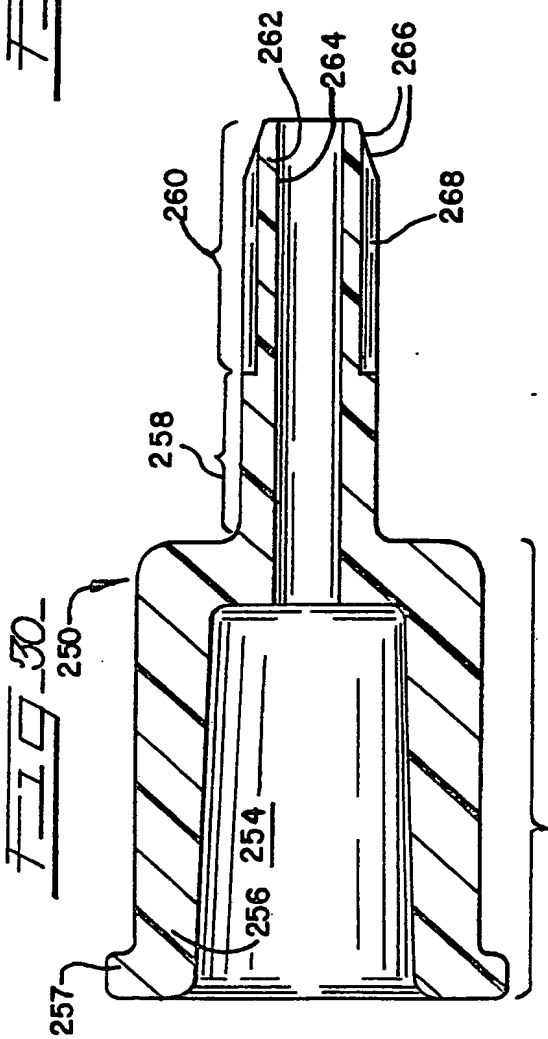


FIG_33

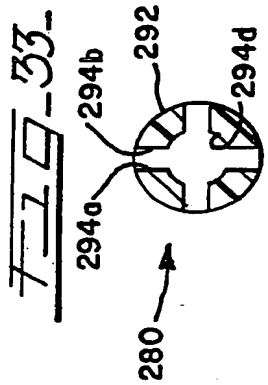
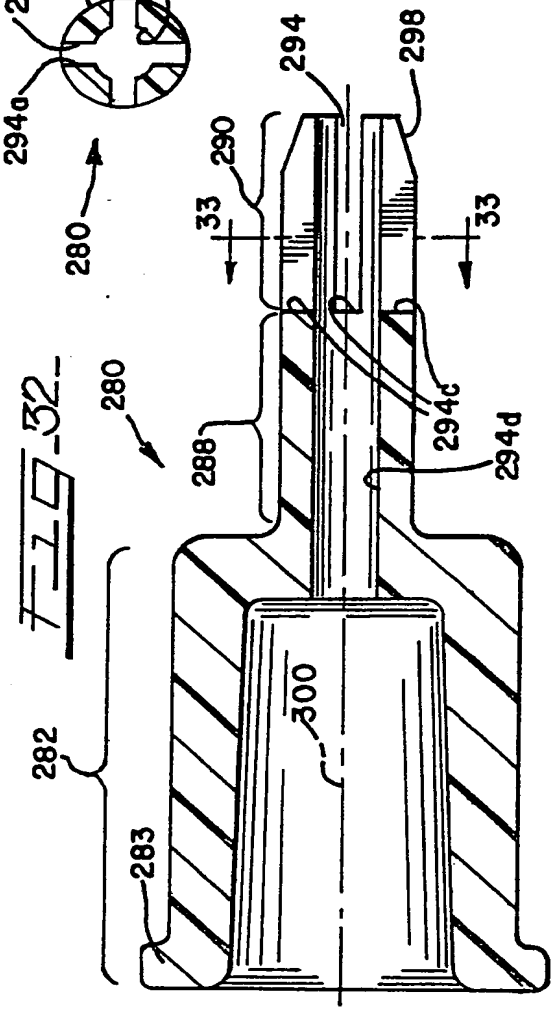


FIG_32



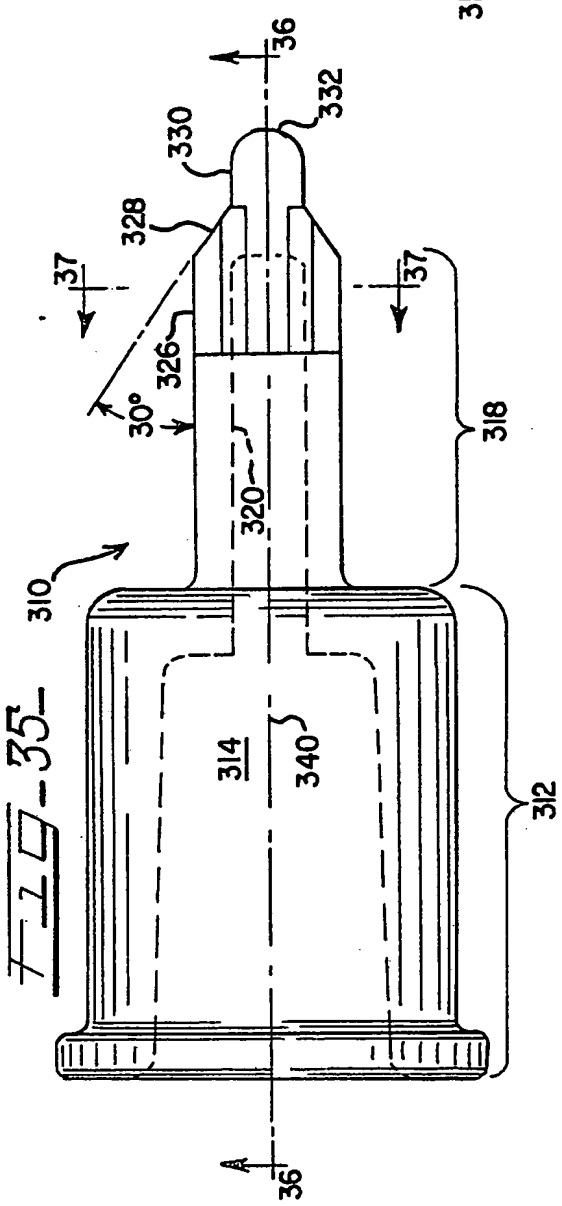


FIG-35

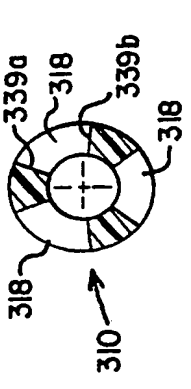


FIG-37

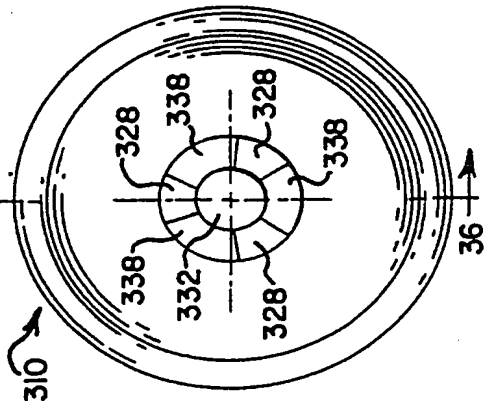


FIG-34

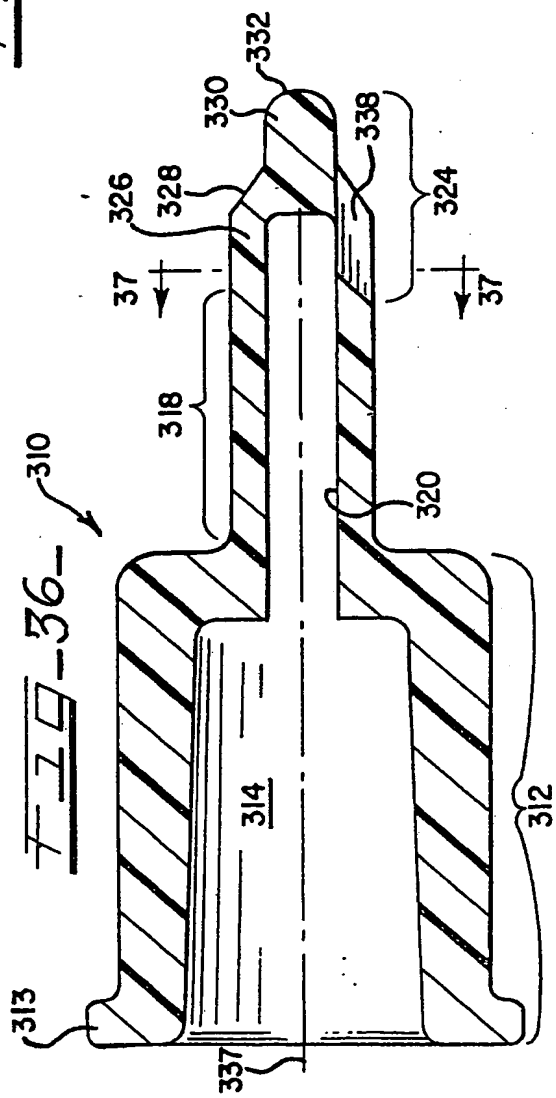


FIG-36

FIG-38

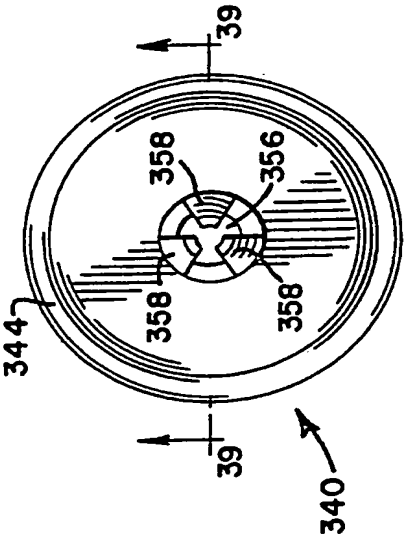


FIG-41

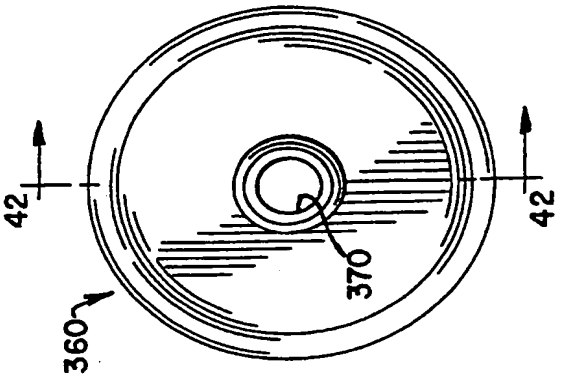


FIG-39

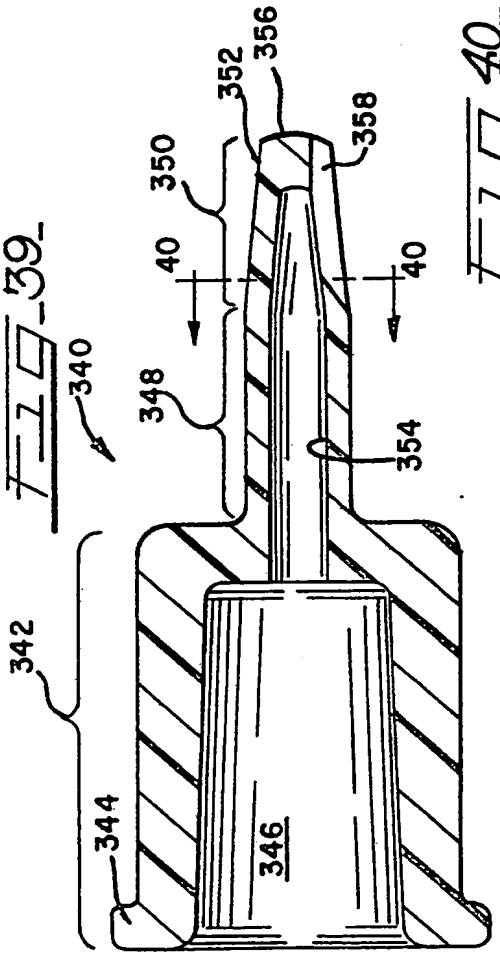


FIG-40

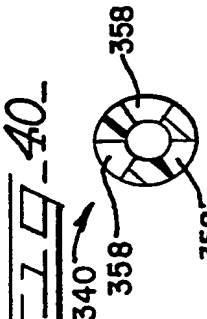
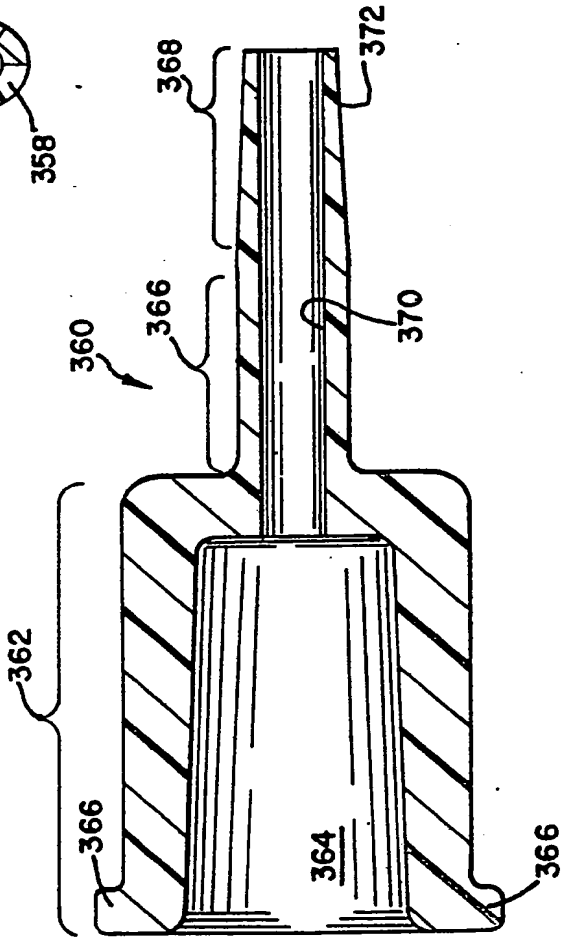


FIG-42



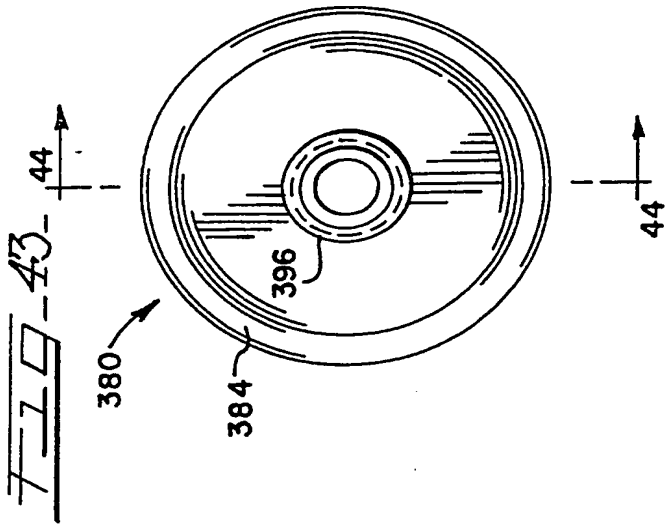


FIG-43

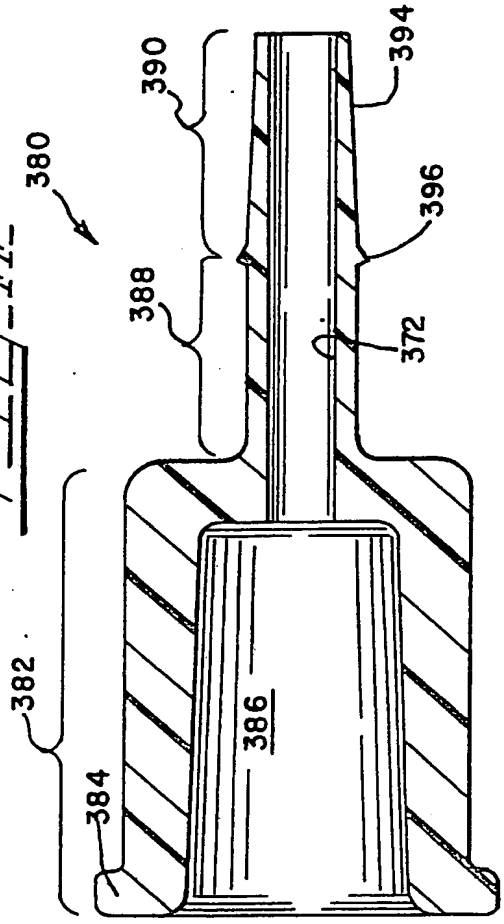


FIG-44

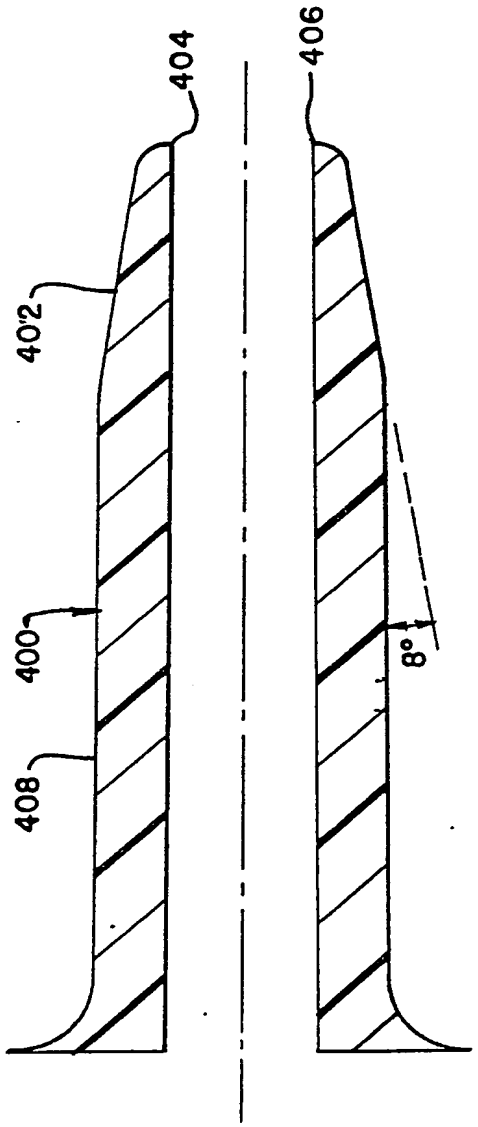


FIG-45

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A61M 37/00, 5/14 — A3

(11) International Publication Number: WO 89/ 06553

(43) International Publication Date: 27 July 1989 (27.07.89)

(21) International Application Number: PCT/US89/00273

(22) International Filing Date: 23 January 1989 (23.01.89)

(31) Priority Application Numbers: 147,414; 217,004

(32) Priority Dates: 25 January 1988 (25.01.88); 8 July 1988 (08.07.88)

(33) Priority Country: US

(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).

(72) Inventors: JEPSON, Steven, C. ; 1352 E. Palatine Road, Palatine, IL 60067 (US). DUDAR, Thomas, E. ; 859 E. Babcock Drive, Palatine, IL 60062 (US). ZDEB, Brain, D. ; 2 E. Lakeshore, Round Lake, IL 60073 (US). DESECKI, Vince, C. ; 28420 W. Big Hollow Rd., Ingleside, IL 60041 (US).

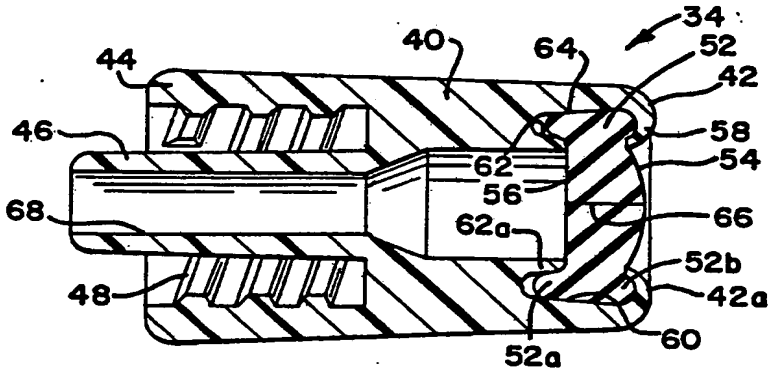
(74) Agents: ROCKWELL, Amy, L., H. et al.; One Baxter Parkway, Deerfield, IL 60015 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report: 2 November 1989 (02.11.89)

(54) Title: PRE-SLIT INJECTION SITE AND TAPERED CANNULA



(57) Abstract

A pre-slit injection site (34) includes a housing (40) with a flow path therethrough. A first end (42) of the housing (40) carries a pre-slit septum (52). One form of a blunt cannula (98), usable with the injection site (34), carries a locking member (100). When the pre-slit injection site (34) slidably receives the blunt cannula (98), the locking member (100) latches to the injection site (34) and creates a mechanically coupled unit. Another form of the cannula (280) includes a tube having a tapered distal end region (298) and having longate discharge slots (294) for reducing contact surface area and for directing the flow laterally out of the cannula. The cannula may also include a rounded lead post (330), an annular barb (394), and axially oriented grooves (268).

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INTERNATIONAL SEARCH REPORT

International Application No PCT/US 89/00273

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 M 37/00, A 61 M 5/14

II. FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
IPC 4	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT *

Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
X	DE, C, 3303718 (B. BRAUN MELSUNGEN) 4 October 1984, see figure 1; claims 1,5,8,10,11	1,3,4,6
Y		9-12
Y	EP, A, 0111723 (INTERMEDIKAT GmbH) 27 June 1984, see figure; claim 2	1,3,6,8
Y		2
Y	DE, A, 3627978 (VEB KOMBINAT MEDIZIN UND LABORTECHNIK) 11 June 1987, see figure 2; column 3, lines 54-59; claims 1,4	1,3,6,8
Y	FR, A, 2539303 (TERUMO K.K.) 20 July 1984, see figure 5; page 8, lines 23-33	2
Y	US, A, 4511359 (VAILLANCOURT) 16 April 1985, see figure 2; column 5, line 59 -	9-12

./.

* Special categories of cited documents: 10

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20th September 1989	11 OCT 1989
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	T.K. WILLIS

III. DOCUMENTS C NSIDERED TO BE RELEVANT (CONTINUED FROM THE SEC ND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
	column 6, line 5	
X	US, A, 2989053 (HAMILTON) 20 June 1961, see column 1, lines 16-19; column 2, lines 46-60; column 4, lines 6-11; figures 1-3,5	13-17
X	EP, A, 0050459 (TRAVENOL) 28 April 1982, see figures 1-4; page 4, lines 15-26	13-17
Y		18,19
Y	FR, A, 1373027 (RAZIMBAUD) 17 August 1964, see figure 10; page 2, right-hand column, lines 19-33	18-19
Y	AU, A, 13945 (FORT DAVID LAB.) 21 October 1971, see figures 1-3; page 4, lines 15-27	18,19,22,23
A	EP, A, 0021405 (ENTERMEDICAT) 7 January 1981, see claims 1,2; figures 1-5	20
Y	FR, A, 2439022 (VIGGO AB) 16 May 1980, see figures 2,3	22-23

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ....., because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers ....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-8: Injection site
Claims 9-12: Coupling system (injection site + cannula)
Claims 13-23: Insertion member
Please refer to Form PCT/ISA 206 dated 19th May 1989

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☒ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 8900273
SA 26594

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 04/10/89
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-C- 3303718	04-10-84	None	
EP-A- 0111723	27-06-84	None	
DE-A- 3627978	11-06-87	None	
FR-A- 2539303	20-07-84	JP-A- 59133877	01-08-84
		JP-A- 59164067	17-09-84
		JP-A- 60088562	18-05-85
		BE-A- 898705	16-05-84
		DE-A,C 3401440	13-09-84
		GB-A,B 2135889	12-09-84
		SE-A- 8400162	19-07-84
		US-A- 4610665	09-09-86
US-A- 4511359	16-04-85	None	
US-A- 2989053		None	
EP-A- 0050459	28-04-82	AU-A- 7485681	29-04-82
		CA-A- 1161401	31-01-84
		JP-A- 57203453	13-12-82
		US-A- 4411661	25-10-83
FR-A- 1373027		None	
AU-A- 13945		None	
EP-A- 0021405	07-01-81	None	
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		DE-A,C 2941278	30-04-80
		GB-A,B 2034185	04-06-80
		JP-A- 55076659	09-06-80
		NL-A- 7907646	21-04-80
		SE-A- 7810807	18-04-80
		US-A- 4243034	06-01-81

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